

CURIS INC  
Form 10-K  
March 13, 2013  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark one)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2012

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**  
(State or other jurisdiction of  
incorporation or organization)

**04-3505116**  
(I.R.S. Employer  
Identification No.)

4 Maguire Road

Lexington, Massachusetts 02421

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(Address of principal executive offices) (Zip Code)

617-503-6500

(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, \$0.01 par value per share	The NASDAQ Stock Market

**Securities registered pursuant to Section 12(g) of the Act:**

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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.

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>

(Do not check if a smaller reporting company)

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) based on the last reported sale price of the common stock on June 30, 2012 was approximately \$279,356,000.

As of March 6, 2013, there were 80,122,031 shares of the registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the registrant's proxy statement for the annual meeting of stockholders scheduled to be held on May 30, 2013, which are to be filed with the Commission not later than 120 days after the close of the Registrant's fiscal year ended December 31, 2012 pursuant to Regulation 14A, have been incorporated by reference in Item 5 of Part II and Items 10-14 of Part III of this Annual Report on Form 10-K.



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**PART I**

*This annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause Curis' financial, operating and business results to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including without limitation any expectations of revenue, expenses, earnings or losses from operations, or other financial results; statements with respect to the plans, strategies and objectives of management for future operations; statements concerning product research, development and commercialization plans, timelines and anticipated results; statements of expectation or belief; and statements of assumptions underlying any of the foregoing. The risks, uncertainties and assumptions referred to above include risks that are described in Item 1A-Risk Factors and elsewhere in this annual report and that are otherwise described from time to time in our Securities and Exchange Commission reports filed after this report.*

*The forward-looking statements included in this annual report represent our estimates as of the filing date of this annual report. We specifically disclaim any obligation to update these forward-looking statements in the future. These forward-looking statements should not be relied upon as representing our estimates or views as of any date subsequent to the date of this annual report.*

*Unless otherwise indicated, or unless the context of the discussion requires otherwise, we use the terms we, us, our and similar references to refer to Curis, Inc. and its subsidiaries, on a consolidated basis. We use the terms Curis to refer to Curis, Inc. on a stand-alone basis.*

**ITEM 1. BUSINESS**

**Overview**

We are an oncology-focused company seeking to develop and commercialize next generation targeted small molecule drug candidates for cancer treatment. We conduct our research and development programs both internally and through strategic collaborations. Our lead program is Erivedge<sup>®</sup>, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor that is being developed under collaboration with Genentech, Inc. or Genentech. Erivedge is the first and only U.S. Food and Drug Administration, or FDA, approved medicine for the treatment of advanced basal cell carcinoma, and is being developed and commercialized by F. Hoffmann-La Roche Ltd, or Roche, and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech. In January 2012, the FDA approved the Erivedge capsule for treatment of adults with basal cell carcinoma, or BCC, that has spread to other parts of the body, or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. We refer to this indication as advanced BCC. Erivedge is also the subject of regulatory reviews for potential approval in advanced BCC by several health authorities outside of the U.S., including in Europe and Australia. Erivedge's FDA approval and Roche's regulatory submissions in regards to Erivedge in Europe, Australia, and other territories are based on positive clinical data from ERIVANCE BCC/SHH4476g, a pivotal phase II study of Erivedge in patients with advanced BCC. In addition, Genentech is testing Erivedge in clinical trials to treat less severe forms of BCC. Third-party investigators are also conducting clinical trials with Erivedge in BCC as well as in several other cancers.

We are developing the following targeted cancer drug candidates in clinical trials:

In November 2012, we licensed from Genentech the exclusive, worldwide rights for the development and commercialization a small molecule drug candidate, CUDC-427, which is designed to promote cancer cell death by antagonizing inhibitors of apoptosis, or IAP, proteins. 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 and we currently expect to initiate clinical studies of this drug candidate during 2013.

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We recently initiated clinical development of CUDC-907, an orally bioavailable small molecule drug candidate that is designed to inhibit phosphatidylinositol-3-kinase, or PI3K, and histone deacetylase, or HDAC, enzymes. In November 2011, we entered into an agreement with The Leukemia & Lymphoma Society, or LLS, under which LLS will make milestone payments of up to \$4,000,000 to support the Company's ongoing development of CUDC-907 in patients with relapsed or refractory lymphomas and multiple myeloma. In January 2013, we treated the first patient in a phase I clinical study of CUDC-907 and as of March 6, 2013, the first cohort of 3 patients has been enrolled in this study.

We are a party to a license agreement with Debiopharm S.A., or Debiopharm, pursuant to which Debiopharm is developing heat shock protein 90, or HSP90, inhibitor Debio 0932. Debio 0932 recently completed phase Ib testing in patients with advanced solid tumors and Debiopharm is also currently testing Debio 0932 in a phase I/II clinical trial in patients with advanced non-small cell lung cancer, or NSCLC. Debiopharm plans to initiate a phase I study of Debio 0932 in patients with renal cell carcinoma in the second half of 2013.

We are developing CUDC-101, a first-in-class small molecule drug candidate designed to simultaneously target the epidermal growth factor receptor, or EGFR, human epidermal growth factor receptor 2, or HER2, and HDAC, each of which is a validated cancer target and important for cancer formation and maintenance. An intravenous formulation of CUDC-101 is currently being tested in a phase I clinical trial in patients with locally advanced squamous cell carcinoma of the head and neck, or SCCHN in combination with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation.

In December 2012, through our subsidiary Curis Royalty, LLC, or Curis Royalty, we received a \$30,000,000 loan at an annual interest rate of 12.25% pursuant to a credit agreement with BioPharma Secured Debt Fund II Sub, S.à r.l., or BioPharma-II, a Luxembourg limited liability company managed by Pharmakon Advisors. Under the terms of the credit agreement, our right to certain future royalty and royalty-related payments on the commercial sales of Erivedge will be transferred by Curis Royalty to BioPharma-II to repay the loan.

**Product Development Programs**

We are developing drug candidates designed to treat cancer. Our product development initiatives, described in the chart below, are being pursued using our internal resources or through our collaboration with Genentech, under our license agreement with Debiopharm and our agreement with LLS. We believe that our collaborators provide significant additional resources and clinical development expertise to our programs.

Our development programs, both internal and under collaboration, are summarized in the following table:

<b>Drug candidate</b>	<b>Primary Disease</b>	<b>Collaborator/Licensee</b>	<b>Status</b>
<b><i>Hedgehog Pathway Inhibitor</i></b>			
- Erivedge	Advanced BCC	Genentech	FDA approved;
			Regulatory submissions pending in EU, Australia and other territories
- Erivedge	Operable Nodular BCC	Genentech	Phase II
<b><i>Antagonist of IAP Proteins</i></b>			
- CUDC-427	Breast cancer and other solid tumors and hematological cancers	Internal development	Completed Phase I
<b><i>Dual PI3K and HDAC Inhibitor</i></b>			
- CUDC-907	Advanced lymphoma and multiple myeloma	Internal development/LLS	Phase I
<b><i>EGFR/HER2 and HDAC Inhibitor</i></b>			
- CUDC-101	Locally advanced SCCHN	Internal development	Phase I
<b><i>HSP90 Inhibitor</i></b>			
- Debio 0932	Advanced NSCLC	Debiopharm	Phase I/II
- Debio 0932	Solid tumor cancers	Debiopharm	Phase Ib



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Since our inception in 2000, substantially all of our revenues have been derived from collaborations and other agreements with third parties. For the years ended December 31, 2012 and 2011, milestone and royalty payments from Genentech accounted for \$15,893,000, or 94%, and \$14,388,000, or 97%, respectively, of our revenue, all of which is related to the development and commercialization of Erivedge. For the year ended December 31, 2010, Debiopharm and settlement proceeds received from a former collaborator, Micromet, accounted for substantially all of our revenue, as follows: Debiopharm, \$11,333,000, or 71%, and Micromet, \$4,000,000, or 25%.

### ***Erivedge® (Hedgehog Pathway Inhibitor)***

The Hedgehog pathway is normally active during embryonic development and regulates tissue and organ formation by directly promoting cell division in specific cell types, and by activating other secondary signaling pathways that control the synthesis of growth promoting and angiogenic (blood vessel-forming) factors. Unregulated activation of the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of cancer cells and leading to formation and maintenance of certain cancers, including BCC and medulloblastoma as well as colorectal, ovarian, pancreatic, small cell lung and breast cancers, among others.

Erivedge, which is also referred to as vismodegib, GDC-0449 and RG3616, is designed to selectively inhibit the Hedgehog signaling pathway by targeting a protein called Smoothened. The Hedgehog signaling pathway plays an important role in regulating proper growth and development in the early stages of life and becomes less active in adults. However, genetic mutations that lead to reactivation of Hedgehog signaling are found in BCC and medulloblastomas. Many other cancer types show abnormally high levels of Hedgehog pathway members in the absence of a mutation. Aberrant signaling in the Hedgehog pathway is implicated in over 90% of BCC cases.

Erivedge, which is FDA-approved for adults with advanced forms of BCC, is our most advanced program and is being developed in various cancer indications under a June 2003 collaboration agreement with Genentech. Genentech and Roche are responsible for the clinical development and commercialization of Erivedge. Erivedge is currently marketed and sold in the U.S., approved for use in Israel and Mexico and is under regulatory review seeking commercialization in Europe, Australia and other territories. In October 2010, Genentech and Roche initiated a phase II clinical trial of Erivedge in operable BCC and expect to complete this study in the first half of 2013. In addition, Erivedge is currently being tested in clinical trials for treatment of other cancers under collaborative agreements between Genentech and either third-party investigators or the U.S. National Cancer Institute, or NCI.

*Advanced BCC.* In January 2012, Erivedge was approved by the U.S. FDA as the first and only FDA-approved medicine for adults with advanced forms of BCC. We earned a \$10,000,000 milestone payment from Genentech as a result of the FDA's approval of Erivedge in this indication. Pursuant to the terms of our collaboration agreement, we are entitled to receive royalties on net sales of Erivedge that range from 5% to high single digits, and which escalate within this range with increasing product sales. The royalty rate applicable to Erivedge may be decreased to a low-to-mid single digit royalty 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.

In November 2012, in connection with a \$30,000,000 loan at an annual interest rate of 12.25% made by BioPharma-II to Curis Royalty, we transferred to Curis Royalty our rights to receive (i) royalty payments on the commercial sales of Erivedge owed by Genentech under our collaboration agreement, (ii) certain other royalty-related payments, if any, including amounts owed by Genentech with respect to the underpayment of royalties and accrued interest on payments which are not timely made by Genentech pursuant to the collaboration agreement and (iii) any payments made by Genentech to Curis pursuant to Genentech's indemnification obligations under the collaboration agreement.

The loan from BioPharma-II will be repaid by Curis Royalty from the proceeds of the royalty and royalty-related payments that it receives from time to time from Genentech. Quarterly royalty and royalty-related



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payments from Genentech will first be applied to pay (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis royalty obligations to university licensors, as described below, (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 \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$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 and distribute to Curis remaining royalty and royalty-related amounts in excess of the foregoing caps, if any. 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. As a result, we will continue to record royalty revenue from Genentech but expect the majority, if not all, of such revenues, subject to the above caps, will be used to pay down the loan received from BioPharma-II.

We are also obligated to make payments to university licensors on royalties that we earn in all territories other than Australia in an amount that 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 we earn from Roche's potential future sales of Erivedge in Australia, we will be obligated to make payments to university licensors in an amount that is equal to 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 we receive from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022. From the inception of our Genentech collaboration through December 31, 2012, we have incurred expenses in an aggregate amount of approximately \$2,926,000 pursuant to licensing agreements with universities related to payments that we have received from Genentech. In addition, we were obligated to issue 200,000 shares of our common stock to two university licensors upon FDA approval of Erivedge that represented \$964,000 in expense during 2012.

We recognized \$1,530,000 of royalty revenue from Genentech's net sales of Erivedge during the year ended December 31, 2012, which amounts were calculated at 5% of Genentech's net Erivedge sales. We recorded cost of royalty revenues of \$176,000 during this same period, including a \$100,000 one-time cash payment paid to a university licensor upon the first commercial sale of Erivedge and \$76,000 paid to two university licensors, which represents 5% of the royalties that we earned with respect to Erivedge during the year ended December 31, 2012.

In May 2012, we earned a \$4,000,000 payment in connection with Roche's filing of an application for marketing registration for Erivedge with Australia's Therapeutic Goods Administration, or TGA. During the fourth quarter of 2011, Roche submitted a Marketing Authorization Application, or MAA, for Erivedge to the European Medicines Agency, or EMA, for which we earned a \$6,000,000 payment. Of these amounts, we paid \$950,000, or 9.5%, to our university licensors, which includes one-time payments totaling \$450,000 related to milestones specific to the Australian territory and the remaining \$500,000 represents our ongoing obligation to pay 5% of all payments received from Genentech to our university licensors, pursuant to the terms of our agreements with those institutions. Roche has indicated that it anticipates potential EMA approval for Erivedge during the first half of 2013. Roche has also filed new drug applications for marketing registration with health authorities in several other territories seeking approval for Erivedge in advanced BCC. We will receive additional payments if Erivedge receives EMA and/or TGA marketing authorizations.

*Operable BCC.* Genentech is also conducting a separate phase II clinical trial of Erivedge in patients with operable nodular BCC, which is a less severe form of the disease and accounts for a significant fraction of the approximately two million BCC cases diagnosed annually in the U.S. This phase II trial is the first study to assess whether Erivedge can provide complete clearance of tumor as measured using histological examination. This is an important first step in determining the efficacy of Erivedge in less severe forms of BCC that are

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generally effectively treated surgically. This trial is designed to test different durations of treatment with Erivedge in patients with operable nodular BCC. The study is conducted in the U.S. and is designed as an open label trial enrolling approximately 75 patients in three cohorts. Patients in the first and second cohorts receive a 150 mg daily oral dose of Erivedge for 12 weeks. Patients in the third cohort receive daily doses of Erivedge using the following administration regimen: eight-week of treatment, four weeks of drug holiday, and eight weeks of treatment. The primary outcome measure for the first and third cohorts is the rate of complete histological clearance of the target nodular BCC lesions at the time of tumor excision (which may occur up to 12 or 20 weeks, respectively, following initiation of Erivedge treatment). The primary outcome measure for the second cohort is the rate of durable complete clearance of target nodular BCC lesions at the time of excision (which may occur up to 36 weeks following initiation of treatment).

Initial results from the first cohort were published in a scientific abstract in April 2012 in the *Journal of Investigative Dermatology* and were also presented at the annual meeting of the Society for Investigative Dermatology in May 2012. This first cohort evaluated the safety and efficacy of 12 weeks of daily 150 mg dosing of Erivedge in 24 patients with newly diagnosed operable nodular BCC. Patients then underwent Mohs surgery with independent pathology review. Histologically confirmed complete clearance was reported in 10 patients (42%) and clinical complete and partial responses were reported for 23 patients (96%). The most frequent adverse events were similar to those observed in previous studies with Erivedge and included muscle spasms (79%), ageusia/dysgeusia (79%), alopecia (38%), fatigue (21%) and nausea (21%). Most adverse events were of low severity, or Grade 1 to 2 on a scale of 1 to 5; seven patients (29%) reported Grade 3 adverse events, including four patients with muscle spasm. No serious adverse events were reported. Eight patients (33%) discontinued the study, including two (8%) due to adverse events. Cohorts two and three are fully enrolled and full study results are expected during the first half of 2013.

*Other Erivedge Clinical Trials.* In addition to the BCC clinical trials being conducted directly by Genentech and Roche, Erivedge is also currently being tested in other cancers in trials under collaborative agreements between Genentech and either third-party investigators or the NCI.

*Genentech Hedgehog Pathway Inhibitor Collaboration Agreement.* Under the terms of our June 2003 collaborative research, development and license 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 pathway inhibitors for human therapeutic applications, including cancer therapy. Genentech subsequently granted a sublicense to Roche for non-U.S. rights to Erivedge. Roche received this sublicense pursuant to an agreement between Genentech and Roche under which Genentech granted Roche an option to obtain a license to commercialize certain Genentech products in non-U.S. markets. In February 2010, Chugai Pharmaceutical Co., Ltd., or Chugai, exercised its right of first refusal for the development and commercialization of Erivedge in Japan pursuant to an existing agreement between Roche and 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 \$46,000,000 to date. We are also eligible to receive royalties on sales of any Hedgehog pathway inhibitor products that are successfully commercialized by Genentech and Roche. Future royalty payments related to Erivedge will service the outstanding debt and accrued interest to BioPharma-II, up to the quarterly caps for 2013, 2014 and 2015, and until the debt is fully repaid thereafter.

Unless terminated earlier, the agreement will expire six months after the later of the expiration of Genentech's obligation to pay royalties to us under the agreement or such time as no activities have occurred under the agreement for a period of twelve months. The agreement may be terminated earlier by either party for cause upon sixty days prior written notice. In addition, Genentech may terminate the agreement, either in whole

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or in part, without cause, upon six months prior written notice. In the event of any termination where specific license grants survive, we will continue to have the right to receive clinical development and regulatory approval milestones and royalties on product sales for such licensed compound, if any. If we terminate the agreement for cause or Genentech terminates the agreement without cause, all licenses granted to Genentech automatically terminate and revert to us. In addition, Genentech has agreed that it will no longer conduct any development or commercialization activities on any compounds identified during the course of the agreement for so long as such compounds continue to be covered by valid patent claims.

***Our Targeted Drug Candidates***

Human cancers are shown to have genetic alterations in components of multiple, intersecting signaling pathways, or networks, that are selected over several generations of cell division and support survival, growth, and invasion of the cancer cell. These genetic alterations afford the cancer cell a malignant phenotype, which results in the formation and maintenance of a tumor. We believe that targeting these critical components and signaling pathways, either singly or in combination, could provide more effective drugs and improve outcomes for cancer patients. We are developing small molecule drug candidates that are designed and discovered internally or acquired through license, which target a number of critical components and pathways altered in different human cancers.

*CUDC-427.* 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. IAP proteins are a family of functionally and structurally related proteins that promote cancer cell survival by inhibiting programmed cell death, also known as apoptosis, which is a normal process inherent in every cell. Using IAP proteins and other anti-apoptotic factors, cancer cells evade apoptosis in response to a variety of signals, including those provided by anti-cancer agents such as chemotherapy, or naturally occurring inflammatory and immune signals transmitted through members of tumor necrosis factor, or TNF, family of factors. Evasion from apoptosis is a fundamental mechanism whereby human cancers develop resistance to standard anti-cancer treatments. IAP inhibitors such as CUDC-427 are designed to counteract the effects of IAP proteins, thus shifting the balance away from cancer cell survival and allowing apoptosis to proceed.

Prior to our license, Genentech had completed enrollment in a phase I clinical trial of CUDC-427, previously named GDC-0917, in which 42 patients received daily oral doses of CUDC-427 for two weeks, followed by a one week rest period until disease progression or study discontinuation for any other reason. Genentech plans to present full study results at a medical conference in mid-2013. We plan to continue the further clinical development of CUDC-427 and to initiate additional clinical studies in 2013.

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. We incurred expenses of \$9,500,000 upon entry into this license agreement with Genentech, representing an up-front license payment and technology transfer costs. In addition, Genentech will be entitled to receive milestone payments upon the first commercial sale of CUDC-427 in certain territories and a tiered single digit royalty on net sales of CUDC-427, if any. The IAP license agreement will continue to be in effect until expiration of all royalty payment obligations with respect to any product, unless terminated early by either party as described below. Upon expiration of the agreement, the Company's license will become royalty-free, fully paid-up, irrevocable and perpetual.

Both we and Genentech may terminate the IAP license agreement prior to expiration in the event of the uncured material breach of the agreement by the other party. In addition, we may terminate the IAP license agreement prior to expiration for any reason upon 90 days prior written notice to Genentech. Upon any termination of the IAP license agreement, the license granted to us will terminate and revert to Genentech. If Genentech terminates the IAP license agreement for an uncured material breach by us, or if we terminate the

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agreement for any reason other than uncured material breach by Genentech, Genentech will be entitled to certain licenses and other rights with respect to products existing as of the date of termination, and we may, under specified circumstances, be obligated to supply products to Genentech for a limited period after termination.

*CUDC-907.* CUDC-907 is a small molecule targeted drug candidate designed and discovered by us to inhibit PI3K, and HDAC enzymes. Concurrent inhibition of PI3K and HDAC has synergistic effect in certain preclinical cancer models, and based on published observations of clinical activity of such agents in hematological and other cancers. CUDC-907 has demonstrated potent antitumor activity in a variety of hematological tumor models including non-Hodgkin's lymphoma and multiple myeloma.

In November 2011, we entered into an agreement under which The Leukemia & Lymphoma Society, or LLS, will provide up to \$4,000,000 in milestone payments to support our ongoing development of CUDC-907. In January 2013, we treated the first patient in a phase I clinical study of CUDC-907 in patients with advanced lymphoma and multiple myeloma. The phase I clinical trial is designed as a standard dose escalation study in which CUDC-907 will be orally administered to patients with relapsed or refractory lymphoma or multiple myeloma. The primary objectives of the trial are to determine the maximum tolerated dose, or MTD, and recommended phase II dose for CUDC-907 administration. The secondary objectives of this study are to assess safety and tolerability, to assess pharmacokinetics, to evaluate biomarker activity and to assess preliminary anti-cancer activity of CUDC-907 in this patient population. In the absence of dose limiting toxicity, each patient will receive CUDC-907 orally once daily for a minimum of 21 days (1 cycle), and may continue to receive additional cycles of treatment until disease progression or other treatment discontinuation criteria are met. Through March 6, 2013, we have earned \$1,100,000 in milestone payments under the terms of the agreement with LLS. We will be obligated to make future contingent payments, including potential royalty payments under our agreement with LLS upon our successful entry into a partnering agreement for CUDC-907 or upon the achievement of regulatory and commercial objectives, with such payments being limited to a maximum of 2.5 times the actual milestone payments that we receive from LLS under this agreement. If clinical development of 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 by LLS will be considered a non-repayable grant.

The agreement with LLS will remain in effect until the completion of the defined milestones, unless earlier terminated in accordance with the provisions of this agreement, including safety issues related to the administration of CUDC-907, failure to obtain or maintain regulatory approvals for clinical trials, and breach by either party.

In addition to our ongoing phase I clinical study in advanced lymphomas and multiple myeloma patients, we are conducting preclinical studies with CUDC-907 in solid tumor models and we expect that we will initiate additional studies using CUDC-907 in combination with other anti-cancer agents in patients with solid tumors during the second half of 2013.

*CUDC-101.* CUDC-101 is a drug candidate that is designed to target EGFR/HER2 and HDAC. In preclinical studies, CUDC-101 demonstrated the potential to inhibit all three molecular targets resulting in the potent killing of a wide range of cancer cell lines that are representative of a variety of human cancer types, many of which have demonstrated resistance to various approved targeted agents.

To date, we have completed two clinical trials with an intravenous formulation of CUDC-101, including a phase I dose escalation clinical trial of CUDC-101 in 25 patients with advanced, refractory solid tumors and a phase I expansion trial that tested CUDC-101 in 46 patients with specific tumor types, including breast, gastric, head and neck, NSCLC or liver cancers. The phase I expansion trial was designed as an open-label study in which patients were treated with CUDC-101 at the maximum tolerated dose which was determined in the phase I dose escalation study to be 275 milligrams per meter squared of human body surface area (275 mg/m<sup>2</sup>). The

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primary objectives of the expansion study were to assess the safety and tolerability of CUDC-101 in subjects with these specific advanced solid tumors when the drug was administered via one-hour intravenous infusion either on a five days per week schedule (one week on/one week off) or on a three days per week schedule (three weeks on/one week off).

We are currently conducting a phase I clinical trial of CUDC-101 in locally advanced head and neck cancer patients. We have enrolled ten patients in this trial as of March 6, 2013. The primary objectives of this study are to evaluate the safety and tolerability of CUDC-101 when administered in combination with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation. Based on the results of this study, we intend to make a go/no go decision regarding further development of intravenously administered CUDC-101.

In 2012, we initiated a phase I clinical trial of an oral formulation of CUDC-101. We subsequently terminated this study due to insufficient drug exposure observed in the first cohort of patients. We are currently assessing alternative formulations that may provide improved drug exposure for patients, as well as backup molecules whose chemical properties may be more amenable to the oral route of administration.

*Debio 0932.* HSP90 is a member of a class of proteins called molecular chaperones that play a fundamental role in the proper folding, stabilization and degradation of other cellular proteins under normal or stressful conditions. HSP90, in particular, has become an attractive therapeutic target for the treatment of cancer because it stabilizes cellular proteins involved in various aspects of cancer cell growth and survival. In preclinical studies, tumor regressions were observed after treatment of acute myelogenous leukemia, breast, NSCLC, glioblastoma, gastric and colon cancer models with Debio 0932.

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 has assumed all development responsibility for Debio 0932 and Debiopharm or a Debiopharm licensee will incur all costs related to the development, registration and commercialization of products under the agreement.

In April 2010, Debiopharm initiated a phase I clinical trial to evaluate the safety of Debio 0932 in patients with advanced solid tumors. In 2011, Debiopharm successfully advanced Debio 0932 through the dose escalation portion of this phase I study and presented results of this study at the annual meeting of the American Society of Clinical Oncology in June 2012. In this portion of the study, Debio 0932 was tested in 50 patients, including 22 patients who received Debio 0932 every other day and 28 patients who received daily dosing of Debio 0932. Debio 0932 was generally well tolerated in this study, with most adverse events classified as Grade 1 or 2, or mild to moderate severity, with no apparent dose or schedule relationship. In addition, no ocular or cardiac toxicities were observed and no consistent changes in hematology or biochemistry parameters were seen. The most common adverse events included asthenia, constipation, decreased appetite, diarrhea, nausea, and vomiting. Anti-tumor activity was assessed in 45 of the 50 patients enrolled in this study, including a partial response observed in a patient with Kras-mutated lung cancer and in one patient with breast cancer. Stable disease was observed in 12 patients and disease progression was observed in the remaining 31 patients evaluable for efficacy evaluation.

In 2012, Debiopharm advanced Debio 0932 into the phase Ib expansion portion of the study, which has now been completed and enrolled approximately 30 patients with advanced solid tumors, including patients with advanced NSCLC. We anticipate that Debiopharm will present data from this study at a medical meeting during the second half of 2013.

In August 2012, Debiopharm initiated the HSP90 inhibition and lung cancer outcomes, or HALO, study. This study is a phase I/II clinical trial of the safety and efficacy of Debio 0932 in combination with standard of care first- and second-line chemotherapy agents in patients with advanced, stage IIIb or IV NSCLC that is characterized as wild-type EGFR. The phase I portion of this trial is designed to determine the recommended phase II dose of Debio 0932 when given in combination with cisplatin/pemetrexed or cisplatin/gemcitabine in treatment-naive patients, and with docetaxel in previously treated patients. Assuming the phase I trial is

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completed successfully and the recommended phase II dose of Debio 0932 in combination with each of the three chemotherapy regimens has been identified, Debiopharm expects to conduct a randomized, double-blind, placebo-controlled phase II portion of this study where approximately 140 eligible patients will be randomized to receive chemotherapy in combination with either placebo or Debio 0932.

In addition, Debiopharm has recently indicated that it plans to initiate another phase I study in patients with renal cell carcinoma, or RCC during the second half of 2013.

Pursuant to the terms of our agreement with Debiopharm, we received an up-front license fee of \$2,000,000. In addition, during 2010, we earned \$11,000,000 in payments upon Debiopharm's successful achievement of clinical and regulatory objectives, including the approval from French regulatory authorities of Debiopharm's clinical trial application, or CTA, to begin phase I clinical trials and the treatment of the fifth patient in this trial. We are eligible to receive up to an additional \$77,000,000 if specified clinical development and regulatory approval objectives are met. We are eligible to receive milestone payments under our license agreement with Debiopharm if and when Debiopharm treats its fifth patient in up to three phase II clinical trials, assuming that Debiopharm advances Debio 0932 into phase II clinical testing. We currently anticipate that phase II testing could commence in the NSCLC study in 2014. We are also eligible to receive royalties if any products under the license agreement are successfully developed and commercialized. For net sales of Debio 0932 that are made directly by Debiopharm, we are entitled to a high single digit to low double digit royalty, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to Debio 0932 may be reduced. We are entitled to a share of any royalties that Debiopharm receives from a sublicensee.

The agreement is effective as of August 5, 2009, and unless terminated earlier will expire, on a country-by-country basis, on the later of (i) the expiration of the last-to-expire valid claim of the Curis patents and joint patents relating to the products, and (ii) the 10<sup>th</sup> anniversary of the first commercial sale of the product in such country. Debiopharm may terminate the agreement prior to its expiration at any time for any scientific, technical, administrative or commercial reasons upon 90 days prior written notice to us. If Debiopharm is permanently enjoined from exercising its license under the agreement pursuant to a patent infringement action brought by a third party, or if neither Debiopharm nor we undertake the defense or settlement of a third party suit alleging infringement within the six-month period after notice of such suit, then Debiopharm may terminate the agreement in the country where such suit was filed upon thirty days' prior written notice to us. If Debiopharm does not correct a failure to use reasonable commercial efforts as set forth in the agreement, we may terminate the agreement on thirty days' written notice to Debiopharm unless Debiopharm cures such failure before the end of such thirty day period. Either party may terminate the agreement prior to its expiration subject to certain conditions, upon 90 days (or 45 days in the case of failure to make payment of amounts due under the agreement) prior written notice to the other party in the event of the material breach of any term or condition of the agreement by the other party, unless the breaching party has cured such breach by the end of the applicable cure period; and immediately upon written notice to the other party if the other party or its affiliate directly, or through assistance granted to a third party, challenges, whether as a claim, a cross-claim, counterclaim, or defense, the validity or enforceability of any of such party's patents before any court, arbitrator, or other tribunal or administrative agency in any jurisdiction.

## **Corporate Information**

We were organized as a Delaware corporation in February 2000. We began our operations in July 2000 upon the completion of the merger of Creative BioMolecules, Inc., Ontogeny, Inc. and Reprogenesis, Inc. Our principal executive office is located at 4 Maguire Road, Lexington, MA 02421 and our telephone number is (617) 503-6500.

Curis is our trademark and Erivedge is a trademark of Genentech. This annual report on Form 10-K may also contain trademarks and trade names of others.

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### **Website Access to Reports**

We maintain a website with the address [www.curis.com](http://www.curis.com). We are not including the information contained in our website as part of, or incorporating it by reference into, this annual report on Form 10-K. Our website address is included in this annual report on Form 10-K as an inactive textual reference only. We make available free of charge through our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, current reports on Form 8-K and any such amendments to those reports as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission, or the SEC. The SEC maintains a website, [www.sec.gov](http://www.sec.gov), that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The public may read and copy any materials we file with the Securities and Exchange Commission at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the public reference room by calling 1-800-SEC-0330. In addition, we provide paper copies of our filings free of charge upon request. We also make available on our website our corporate governance guidelines, the charters for our audit committee, compensation committee and nominating and corporate governance committee, and our code of business conduct and ethics, and such information is available in print to any stockholder of Curis who requests it.

### **Intellectual Property**

Our policy is to obtain and enforce the patents and proprietary technology rights that are key to our business. We intend to continue to file U.S. and foreign patent applications to protect technology, inventions and improvements that are considered important to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

In the U.S., we have 95 issued or allowed patents expiring on various dates between 2013 and 2030 as well as numerous pending patent applications. We have foreign counterpart patent filings for most of our U.S. issued patents and patent applications. These patents and patent applications are directed to various inventions including compositions of matter, methods of making and using these compositions for multiple applications, methods for drug screening and discovery, developmental biological processes, and patents which relate to our proprietary technologies.

*Hedgehog Pathway.* We have 79 issued U.S. patents or allowed U.S. applications expiring on various dates between 2013 and 2030, which relate to the Hedgehog pathway. Our patents and patent applications cover proteins, nucleic acids, antibodies, and certain small molecule agonists and inhibitors of the Hedgehog pathway, drug screening and discovery methods, methods of protein manufacturing, as well as methods of using the aforementioned proteins, nucleic acids, antibodies or small molecules to activate or inhibit the Hedgehog pathway for a variety of therapeutic indications or diagnostic uses. In addition, we have filed foreign patent applications corresponding to many of the aforementioned U.S. filings that could provide additional patent protection for products that activate or inhibit the Hedgehog pathway.

Our academic and research institution collaborators have certain rights to publish data and information regarding their discoveries to which we have rights. While we believe that the prepublication access to the data developed by our collaborators pursuant to our collaboration agreements will be sufficient to permit us to apply for patent protection in the areas in which we are interested in pursuing further research, there is considerable pressure on such institutions to rapidly publish discoveries arising from their efforts. This may affect our ability to obtain patent protection in the areas in which we may have an interest. In addition, these collaboration agreements typically contain provisions that provide us with, at a minimum, an option to license the institution's rights to intellectual property arising from the collaboration.

*Targeted Drug Candidates.* We have exclusively licensed worldwide rights from Genentech which cover the IAP inhibitor CUDC-427 (formerly GDC-0917). The portfolio includes two issued U.S. patents which expire in 2025 and which cover a genus of compounds which embrace CUDC-427 and their method of use. The

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licensed portfolio additionally includes a narrower U.S. patent application which specifically covers CUDC-427, as well as pharmaceutical compositions and methods of use thereof. The exclusively licensed portfolio also includes rights to foreign filings corresponding to the aforementioned U.S. filings. In addition to the licensed patents covered CUDC-427, we have 11 issued or allowed U.S. patents which expire on various dates between 2027 and 2029, and several U.S. and foreign utility patent applications directed to our targeted inhibitor classes of novel small molecules, as well as U.S. and foreign patent applications which generically claim the platform concept itself. Our patents and patent applications cover compositions of matter, methods of manufacturing these molecules, formulations, and methods of using these molecules to treat a variety of therapeutic indications. We intend to continue to file additional U.S. and foreign applications as the programs progress.

We are party to various license agreements that give us rights to commercialize various technologies, particularly our Hedgehog pathway technologies, and to use technologies in our research and development processes. The consideration payable in exchange for these licenses includes up-front fees, issuances of shares of common stock, annual royalties, milestone payments and royalties on net sales by our sub-licensees and us. The licensors may terminate these agreements if we fail to meet certain diligence requirements, fail to make payments or otherwise commit a material breach that is not cured after notice.

In addition, we depend upon trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship to us.

### **Research and Development Program**

We have a research group that seeks to identify and develop new therapeutic products and applications thereof for our existing proprietary portfolio and seeks to identify novel compounds able to modulate additional molecular targets that may have therapeutic potential. As of December 31, 2012, our research and development group consisted of 22 employees, including molecular biologists, cell biologists, chemists, pharmacologists and other scientific disciplines.

The amounts spent on company-sponsored research and development activities for the years ended December 31, 2012, 2011 and 2010 were \$15,492,000, \$13,693,000 and \$11,373,000, respectively. We had no collaborator-sponsored research and development expense for the years ended December 31, 2012, 2011 and 2010.

### **Regulatory Matters**

#### *FDA Requirements for New Drug Compounds*

Numerous governmental authorities in the U.S. and other countries extensively regulate, among other things, the research, testing, manufacture, distribution, import and export and marketing of drug products. In the U.S., drugs are subject to rigorous regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, labeling, promotion, sampling and marketing and distribution of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject a company to a variety of administrative or judicially imposed sanctions. These sanctions could include, among other things, the FDA's refusal to approve pending applications, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution.



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The steps ordinarily required before a new pharmaceutical product may be marketed in the U.S. include preclinical laboratory tests, animal tests and formulation studies under the FDA's good laboratory practice, or GLP, regulations; the submission to the FDA of an investigational new drug application, or an IND, which must become effective before testing in humans, or clinical testing, may commence; approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated; adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought; submission to the FDA of a new drug application, or NDA, seeking approval to market the drug product; satisfactory completion of an FDA advisory committee review, if applicable; satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements; and FDA review and approval of the NDA. Satisfaction of FDA pre-market approval requirements typically takes years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product, including new safety risks, may result in restrictions on the product or even complete withdrawal of the product from the market.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal trials to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of compounds for testing must comply with federal regulations and requirements, including the FDA's GLP regulations. Preclinical testing is highly uncertain and may not be completed successfully within any specified time period, if at all. Further, the successful completion of preclinical trials does not assure success in human clinical trials. The results of preclinical testing are submitted to the FDA as part of an IND application, together with manufacturing information, analytical and stability data of the drug formulation, and other information. The IND application must become effective before clinical trials can begin in the United States. An IND application becomes effective 30 days after receipt by the FDA unless before that time the FDA places a clinical hold on the trials. In that case, the IND application sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. If these concerns or questions are unresolved, the FDA may not allow the clinical trials to commence.

Clinical trials involve the administration of the investigational drug to healthy human volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, including good clinical practices, under protocols detailing, among other things, the objectives of the trial, the parameters to be used in assessing safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. subjects must be submitted to the FDA as part of the IND application. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In phase I, the initial introduction of the drug into human subjects, the drug is tested to assess metabolism, pharmacokinetics and pharmacological actions and safety, including side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase II usually involves trials in a limited patient population, to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks, and provide preliminary support for the efficacy of the drug in the indication being studied. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in phase II evaluations, phase III trials may be undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population, typically at geographically dispersed clinical trial sites to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. Phase I, phase II or phase III testing of any drug candidates may not be completed successfully within

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any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted in the U.S. The FDA may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the subject. The FDA, an IRB, or a clinical trial sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request that additional clinical trials be conducted as a condition to product approval. Finally, sponsors are required to publicly disseminate information about certain ongoing and completed clinical trials on a government website administered by the National Institutes of Health, or NIH, and are subject to civil money penalties and other civil and criminal sanctions for failing to meet these obligations.

After successful completion of the required clinical testing, generally a new drug application, or NDA, is prepared and submitted to the FDA. FDA approval of the NDA is required before commercial marketing of the product may begin in the United States. The NDA must include the results of extensive preclinical and clinical testing, a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls, and proposed labeling, among other things. In most cases, a substantial user fee must accompany the NDA. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals regarding the timing of its review of NDAs, although the FDA does not always meet these goals. The FDA may also refer applications for novel drugs or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with good clinical practices, or GCPs, and the integrity of the clinical data submitted.

If the FDA's evaluation of the NDA and inspections of the manufacturing facilities and clinical trial sites are favorable, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval testing, including phase IV trials, and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions and restrictions on distribution and use of the drug, which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Once the NDA is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting, submission of periodic reports, and drug sampling and distribution requirements. If new safety issues arise after approval, the FDA may require the company to conduct additional post-market studies to assess the risk, change the labeling to address the risk, or impose distribution and use restrictions under a Risk Evaluation and Mitigation Strategy, or REMS. Additionally, the FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a company generally

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cannot promote a drug for uses that are not approved by the FDA as reflected in the drug's approved labeling, although there are limited opportunities for companies to disseminate balanced, scientific information about off-label uses, such as in response to an unsolicited request by a healthcare practitioner. Moreover, the Department of Justice can bring civil or criminal actions against companies that promote drugs for unapproved uses, based on the Federal Food, Drug, and Cosmetic Act, the False Claims Act and other federal laws governing reimbursement for drugs under the Medicare and Medicaid laws. Monetary penalties in such cases have often been in excess of \$100 million and in some cases have exceeded \$1 billion. In addition, the FDA requires substantiation of any claims of superiority of one product over another including, in many cases, requirements that such claims be proven by adequate and well-controlled head-to-head clinical trials. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to FDA review and approval of a new NDA or NDA supplement before the change can be implemented. Manufacturing operations must continue to conform to cGMPs after approval. Drug manufacturers are required to register their facilities and list their products with the FDA and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

If the FDA's evaluation of the NDA submission, manufacturing facilities or clinical trial sites is not favorable, the FDA may refuse to approve the NDA or issue a complete response letter. The complete response letter outlines the deficiencies in the submission and may require additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of a NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

### *Foreign Regulation of New Drug Compounds*

Approval of a drug product by comparable regulatory authorities will be necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. While clinical data generated in the U.S. may be accepted in many foreign jurisdictions in lieu of early stage clinical trials (phase I), the approval procedure varies among countries and can involve requirements for additional testing equivalent to phases II and III. The time required may differ from that required for FDA approval and may be longer than that required to obtain FDA approval. There can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed.

In Europe, marketing authorizations may be submitted under a centralized or decentralized procedure. The centralized procedure is mandatory for the approval of biotechnology products and many pharmaceutical products, and provides for the grant of a single marketing authorization, which is valid in all European Union member states. The decentralized procedure is a mutual recognition procedure that is available at the request of the applicant for medicinal products that are not subject to the centralized procedure.

### *Hazardous Materials*

Our research and development processes involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products.

### **Competition**

Our drug candidates, if approved, will compete with existing and new products being developed by others for treatment of the same indications. Competition in the development of human therapeutics and, in particular,

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human therapeutics that target signaling pathways to treat cancers, is intense. Our competitors include large pharmaceutical and biopharmaceutical companies, as well as specialized biotechnology firms, that are developing cancer therapies in the same indications as we are.

*Hedgehog Pathway Inhibitor Program.* We are aware of several biotechnology and pharmaceutical companies that have drug development programs relating to compounds that modulate the Hedgehog pathway. We believe that there are currently at least five other companies that have progressed Hedgehog pathway inhibitors into clinical development: Eli Lilly and Company, Exelixis, Inc. (in co-development with the Bristol-Myers Squibb Company); Pfizer Inc.; Novartis International AG; and Millennium Pharmaceuticals.

*Targeted Drug Candidates.* There are several companies developing drug candidates that target the same molecular targets and signaling pathways that we are targeting. Many companies are testing drug candidates in the same cancer indications that we are testing. For example, Debiopharm SA, Novartis AG and Tetralogic, Inc. are all developing antagonists of IAP proteins and several companies are investigating HSP90 inhibitors in clinical testing, including, among others, Astex Therapeutics Ltd., Daiichi Sankyo, Esanex, Inc., Kyowa Hakko Kirin Co, Ltd., Novartis International AG, Samus Therapeutics, Inc. and Synta Pharmaceuticals Corp. There are commercially-available drugs that individually target either HDAC, EGFR or HER2, as well as a drug that targets EGFR/HER2. For example, commercially available HDAC inhibitors include Zolinza (vorinostat), which is produced by Merck & Company, and Istodax (romidepsin), which is produced by Celgene Corporation. Approved products that target EGFR or HER2, either individually or in combination include Calpresa (vandetanib), Erbitux (cetuximab), Herceptin (trastuzumab), Iressa (gefitinib), Tarceva (erlotinib), Tykerb (lapatinib) and Vectibix (panitumumab). There are also several drug candidates in clinical testing that are designed to inhibit one or more of these targets. However, we are not aware of other molecules in clinical testing that are designed as one chemical entity to target HDAC, EGFR and HER2 or HDAC and PI3K.

Many of the competing companies have financial, marketing and human resource capacities that are substantially greater than our own, which may provide these competitors with significant advantages over us. Others have extensive experience in undertaking clinical trials, in obtaining regulatory approval to market products, in manufacturing products on a large scale and in effectively promoting products to healthcare providers, health plans and consumers which may enhance their competitive position relative to ours. In addition to competing with pharmaceutical and biotechnology companies, the products we are developing would also compete with those being developed by academic and research institutions, government agencies and other public organizations. Any of these organizations may discover new therapies, seek patent protection or establish collaborative arrangements for products and technologies that are competitive with our products and technologies.

The technologies underlying the development of human therapeutic products are expected to continue to undergo rapid and significant advancement and unpredictable changes. Accordingly, our technological and commercial success will be based, among other things, on our ability to develop proprietary positions in key scientific areas and efficiently evaluate potential product opportunities.

The timing of a product's introduction may be a major factor in determining eventual commercial success and profitability. Early entry may have important advantages in gaining product acceptance and market share. Accordingly, we believe the relative speed with which we or any current or future collaborator can complete preclinical and clinical testing, obtain regulatory approvals, and supply commercial quantities of a product will have an important impact on our competitive position, both in the U.S. and abroad. Other companies may succeed in developing similar products that are introduced earlier, are more effective, or are produced and marketed more effectively, or at a minimum obtain a portion of the market share. For example, our competitors may discover, characterize and develop important targeted cancer molecules before we do, which could have a material adverse effect on any of our related research programs. If research and development by others renders any of our products obsolete or noncompetitive, then our potential for success and profitability may be adversely affected.

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For certain of our programs, we rely on, or intend to rely on, strategic collaborators for support in our research programs and for preclinical evaluation and clinical development of our potential products and manufacturing and marketing of any products. Our strategic collaborators may conduct multiple product development efforts within each disease area that is the subject of our strategic collaboration with them. Our strategic collaboration agreements may not restrict the strategic collaborator from pursuing competing internal development efforts. Any of our drug candidates, therefore, may be subject to competition with a drug candidate under development by a strategic collaborator.

### **Manufacturing**

We have no experience or capabilities in manufacturing. We currently rely on collaborators or subcontractors, and we have no plans to develop our own manufacturing capability. Instead, we plan to continue to rely on corporate collaborators or subcontractors to manufacture products. If any of our current or planned collaborators or subcontractors encounters regulatory compliance problems or enforcement actions for their own or a collaborative product, it could have a material adverse effect on our business prospects.

### **Sales and Marketing**

We have no sales, marketing or distribution experience or infrastructure and we have no current plans to develop such capabilities. We currently plan to rely on corporate collaborators for product sales, marketing and distribution.

### **Employees**

As of December 31, 2012, we had 33 full-time employees, of whom 10 hold a Ph.D. or other advanced scientific or medical degree. Of our employees, 22 are currently involved in research and development. None of our employees is a party to a collective bargaining agreement, and we consider our relations with our employees to be good.

### **Executive Officers of the Registrant**

Our executive officers are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Daniel R. Passeri, MSc., J.D.	52	Chief Executive Officer
Ali Fattaey, Ph.D	48	President and Chief Operating Officer
Michael P. Gray	42	Chief Financial Officer
Mark W. Noel	54	Vice President, Technology Management and Intellectual Property
Maurizio Voi, M.D	55	Chief Medical Officer and Chief Development Officer
Daniel R. Passeri, MSc., J.D.		Mr. Passeri has served as our Chief Executive Officer and as a director since September 2001 and additionally held the title of President from September 2001 to February 2013. From November 2000 to September 2001, Mr. Passeri served as our Senior Vice President, Corporate Development and Strategic Planning. From March 1997 to November 2000, Mr. Passeri was employed by GeneLogic Inc., a biotechnology company, most recently as Senior Vice President, Corporate Development and Strategic Planning. From February 1995 to March 1997, Mr. Passeri was employed by Boehringer Mannheim, a pharmaceutical, biotechnology and diagnostic company, as Director of Technology Management. Mr. Passeri is a graduate of the National Law Center at George Washington University, with a J.D., of the Imperial College of Science, Technology and Medicine at the University of London, with an M.Sc. in biotechnology, and of Northeastern University, with a B.S. in biology.

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Name	Age	Position
Ali Fattaey, Ph.D		From February 2013, Dr. Fattaey has served as our President and Chief Operating Officer. From 2011 until February 2013, Dr. Fattaey served as the President and Chief Executive Officer of ACT Biotech, Inc., a biotechnology company. Dr. Fattaey served as ACT Biotech's Chief Operating and Scientific Officer from 2008 until 2010. From June 2006 until January 2008, Dr. Fattaey served the Director of Science and Technology at the Melanoma Therapeutics Foundation, a non-profit organization. From January 2005 until June 2006, Dr. Fattaey was a strategic consultant for pharmaceutical and biotechnology companies. Dr. Fattaey was previously employed at Sagres Discovery as its Chief Scientific Officer from November 2001 until April 2004 and subsequently as the Senior Vice President of Discovery Research at Chiron Corporation following Chiron's acquisition of Sagres Discovery. Dr. Fattaey was employed by Onyx Pharmaceuticals from January 1994 until June 2001, most recently as its Vice President of Discovery Research. Dr. Fattaey received his Ph.D. in microbiology from Kansas State University in 1989 and was a Research Fellow in Medicine at Harvard Medical School, Massachusetts General Hospital Cancer Center.
Michael P. Gray		Mr. Gray has served as our Chief Financial Officer since December 2006 and additionally held the title of Chief Operating Officer from December 2006 to February 2013. From December 2003 until December 2006, Mr. Gray served as our Vice President of Finance and Chief Financial Officer and served as our Senior Director of Finance and Controller from August 2000 until December 2003. From January 1998 to July 2000, Mr. Gray was Controller at Reprogenesis, Inc., a predecessor biotechnology company. Mr. Gray previously served as an audit professional for the accounting and consulting firm of Ernst & Young, LLP. Mr. Gray is a certified public accountant, holds an M.B.A. from the F.W. Olin Graduate School of Business at Babson College, and has a B.S. in accounting from Bryant College.
Mark W. Noel...		Mr. Noel has served as our Vice President, Technology Management and Intellectual Property since September 2008. From March 2001 until September 2008, Mr. Noel has served as our Vice President, Technology Management and Business Development. From March 2000 to February 2001, Mr. Noel was employed by GeneLogic, as Vice President of Customer Relations. From January 1998 to February 2000, Mr. Noel was employed by GeneLogic as Senior Director of Program Management. From December 1993 to January 1998, Mr. Noel was employed by the U.S. Department of Human Services National Cancer Institute Office of Technology Development (now the NCI Technology Transfer Center), where from July 1997 to January 1998, he served as Acting Deputy Director. From February 1989 to November 1993, Mr. Noel worked as a patent agent at Gist Brocades NV, a supplier of ingredients to the pharmaceutical and food sectors. Mr. Noel holds a B.S. in Chemistry from the University of Maryland.
Maurizio Voi, M.D		Dr. Voi has served as our Chief Medical and Chief Development Officer since November 2011. From October 2009 until November 2011, Dr. Voi was employed by Pfizer, Inc., a pharmaceutical company, as Vice President of Clinical Development and Medical Affairs at the Oncology Business Unit of Pfizer's Global Research and Development site in New York. Dr. Voi joined Pfizer in November 2009 as Thoracic Tumor Strategy Team Leader for Oncology. Prior to joining Pfizer, Dr. Voi served from 1998 to 2009 in several key positions at Bristol-Myers Squibb Company, a pharmaceutical company, most recently as the Executive Director, Global Clinical Development and Medical Affairs, Oncology. From 1987-1999, he served in several roles at Eli Lilly and Company, a pharmaceutical company. Dr. Voi holds an M.D. from the University of Padua, School of Medicine in Italy and practiced medicine at the General Hospital, Dolo in Venice, Italy.

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**ITEM 1A. RISK FACTORS**

**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.**

As of December 31, 2012, we had an accumulated deficit of approximately \$748,505,000. We have incurred net losses of \$16,417,000, \$9,859,000, and \$4,435,000 for the years ended December 31, 2012, 2011 and 2010, respectively. Other than Erivedge, which was approved by the FDA in January 2012 for the treatment of advanced forms of BCC, we have not successfully commercialized any products to date, either alone or in collaboration with others. In December 2012, we, through our subsidiary Curis Royalty, received a \$30,000,000 loan pursuant to a credit agreement with BioPharma-II. Under the terms of the credit agreement, our right to certain future royalty and royalty-related payments on the commercial sales of Erivedge will be transferred by Curis Royalty to BioPharma-II to repay the loan. As a result, 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 transfer such royalties to BioPharma-II, as only royalties received by Curis Royalty that are in excess of this obligation can be transferred to Curis from Curis Royalty. All of our drug candidates other than Erivedge are in early stages of development. 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 principally for CUDC-427, CUDC-907, CUDC-101 and other drug candidates that we may seek to develop in the future, either from our internal discovery efforts or through acquisition from third parties, and to fund our general and administrative costs and expenses.

Other than the loan from BioPharma-II in December 2012, we have historically derived a substantial portion of our operating cash flow from the research funding, milestone payments and royalty revenues that we are entitled to receive under our collaboration agreements with third parties. For the years ended December 31, 2012, 2011 and 2010, our revenues were limited to milestone payments and royalties earned under our current collaboration agreements. Further, we transferred our right to certain future royalty and royalty-related payments on the commercial sales of Erivedge as repayment for a loan Curis Royalty entered into with BioPharma-II. Our ability to generate cash flow to operate our business will depend, in part, on royalty payments from the commercial sale of Erivedge, if any, that are in excess of the obligation to transfer certain royalties to BioPharma-II, and the ability of Erivedge to be approved for commercial sale in other countries, which would result in us becoming eligible to receive additional milestone payments, as well as royalties on any future sales. 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 for our technologies under development;

contingent cash payments that we may receive for the achievement of development objectives under any new collaborations or our existing collaborations with Genentech, Debiopharm and LLS; 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, if any, that exceed the obligation to transfer certain royalties to BioPharma-II, which is approved in the U.S. and is under review for approval in Europe, Australia and other territories by the respective health authorities.

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We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of us receiving payments under such collaborations is highly uncertain, especially in light of the obligation to transfer certain royalties on the commercial sales of Erivedge to BioPharma-II.

We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at December 31, 2012 should enable us to maintain current and planned operations into mid-2015. 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;

the timing, receipt and amount of payments, if any, from current and potential future collaborators, including the level of any royalty payments from sales of Erivedge;

the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates, including the level of any royalty payments from sales of Erivedge;

unplanned costs to prepare, file, prosecute, maintain 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, are highly volatile. Due to this and various other factors, including potentially adverse general market conditions and the early-stage status of our internal development pipeline 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.

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 terminate our establishment of 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.**



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In December 2012, through Curis Royalty, we 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

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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.

Per 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 transaction document proves 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 might 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.

**Raising additional capital may cause dilution to our existing 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. For example, in June 2011 we entered into an At Market Issuance Sales Agreement, or ATM agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which, from time to time, we may offer and sell up to \$20 million of common stock that was registered pursuant to our universal shelf registration statement through MLV pursuant to one or more at the market offerings. In addition, with our prior written approval, MLV may also sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. The market for emerging life science stocks in general, and

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the market for our common stock in particular, is highly volatile. Due to this and various other factors, including adverse general market conditions, the early-stage status of our development pipeline 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, and we may not be able to sell additional shares under the arrangement with MLV at favorable prices, if at all. In addition, the terms of any financing may be dilutive or otherwise adversely affect other rights of our stockholders.

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We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties, however we may not be able to enter into such arrangements on acceptable terms, if at all. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates. For example, in December 2012 we, through Curis Royalty, closed on a loan with BioPharma-II in the principal amount of \$30,000,000. Pursuant to the terms of the credit agreement, our right to certain future royalty and royalty-related payments on the commercial sales of Erivedge were transferred by Curis Royalty to BioPharma-II to repay the loan. If we are unable to obtain additional funding on a timely basis, whether through sales of debt or equity or through third party collaboration or license arrangements, we may be required to curtail or terminate some or all of our development programs.

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

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

the status of our preclinical and clinical development programs;

the level of expenses incurred in connection with our preclinical and clinical development programs, including development costs relating to CUDC-427, CUDC-907 and CUDC-101;

any intellectual property infringement lawsuit or other litigation in which we may become involved;

the implementation of restructuring and cost-savings strategies;

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 may 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 December 31, 2012, we had \$58,701,000 of cash, cash equivalents, marketable securities and long-term investments consisting of cash, money market, commercial paper, corporate debt securities, and government obligations. 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 or marketable securities since December 31, 2012, 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 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 and the general economic downturn.

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

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

In January 2012, Erivedge was approved by the FDA as the first and only FDA-approved medicine for people with advanced BCC. Genentech and/or Roche have also filed regulatory submissions in several other territories seeking approval to commercialize Erivedge for this same indication. Genentech and Roche are also conducting a phase II clinical trial of Erivedge in operable nodular BCC and Erivedge is currently being tested in other cancers under collaborative agreements between Genentech and either third-party investigators or the NCI. Our near-term prospects substantially depend upon Genentech's ability to successfully develop and commercialize Erivedge in one or more 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 not accepted as safe, efficacious, cost-effective, and preferable to current therapies in the medical community and by third-party payors;

Genentech and/or Roche fails 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 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 develop, validate and maintain a commercially viable manufacturing process for Erivedge that is compliant with current good manufacturing practices;

Genentech and/or Roche do not successfully obtain third party reimbursement and generate commercial demand that results in sales of Erivedge for advanced BCC in any geographic areas where requisite approvals have been, or may be, obtained;

we or Genentech and/or Roche encounter any third party patent interference 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;

new safety risks are identified after Erivedge is commercially marketed; and/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 will only realize royalty revenue under our collaboration agreement with Genentech to the extent Genentech and Roche successfully commercialize Erivedge in the advanced BCC indication such that net sales are generated at a level sufficient to derive royalties in excess of the obligation to transfer such royalties to BioPharma-II.

**The therapeutic efficacy of targeted drug candidates being developed is unproven in humans, and we may not be able to successfully develop and commercialize CUDC-427, CUDC-907, CUDC-101, Debio 0932 or any other drug candidates pursuant to these programs.**

Our targeted drug candidates, including CUDC-427, CUDC-907, CUDC-101 or Debio 0932, are novel compounds 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

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the successful development and eventual commercialization of our drug candidates. Continued development and eventual commercialization is subject to many potential risks. The drug candidates may not prove to be effective inhibitors of the cancer 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. The drug candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. If our drug candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to 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. Many compounds 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. As a result of these and other risks described herein that are inherent in the development 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 CUDC-427, CUDC-907, CUDC-101 or Debio 0932, or any other targeted 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 identify for specific indications. As a result, we may forego or delay pursuit of opportunities with 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 development of certain of our programs. If one or more of our collaborators fails or delays in developing or 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 pathway technologies. In January 2012, Genentech obtained FDA approval to commercialize Erivedge, the sole compound being developed under this collaboration, in advanced BCC. Genentech and Roche are also conducting, both alone and in collaboration, further studies of Erivedge for other indications. In addition, we entered into a license agreement with Debiopharm pursuant to which Debiopharm is testing Debio 0932 in a phase Ib clinical trial in advanced solid tumors and in a phase I/II clinical study in patients with advanced NSCLS. Debiopharm also has plans to initiate a phase I/II study in patients with renal cell carcinoma. Our collaboration agreement with Genentech and our license agreement with Debiopharm are our most significant collaborations, and these collaborations may not be scientifically or commercially successful due to a number of factors, including the following:

Genentech and Debiopharm each have significant discretion in determining the efforts and resources that they will apply to their respective collaboration with us. The timing and amount of any cash payments related to royalties, if any, and the achievement of development objectives that we may receive under such collaborative arrangements will depend on, among other things, our collaboration partners' efforts, allocation of resources and successful development and commercialization of our drug candidates under their respective agreements with us.

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Our agreements with Genentech and Debiopharm each permits the other party wide discretion in deciding which drug candidates to advance through the clinical trial process. It is possible for Genentech or Debiopharm to reject drug candidates at any point in the research, development and clinical trial process, without triggering a termination of the applicable agreement. In the event of any such decision, our business and prospects may be adversely affected and we may not have the commercial rights or the resources necessary to advance such programs on our own.

We have granted clinical development rights to Genentech and Debiopharm, respectively, under our agreements with each of them. If they fail to allocate sufficient time, attention and resources to clinical trials of drug candidates under these collaborations, or fail to comply with good clinical practices or other applicable regulatory requirements for such clinical trials, the successful clinical development and commercialization of such drug candidates is likely to be adversely affected, as will our ability to generate revenue from such collaborations.

Genentech or Debiopharm 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 and Debiopharm each are seeking to develop several other cancer drug therapies.

Genentech or Debiopharm may change the focus of its development and commercialization efforts or pursue higher-priority programs. Our ability to successfully commercialize drug candidates under collaboration with Genentech or Debiopharm could be limited if Genentech or Debiopharm decreases or fails to increase spending related to such drug candidates.

Debiopharm may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or change of control. Any such transaction could divert the attention of our collaborative partner's management and adversely affect its ability to retain and motivate key personnel who are important to the continued development of the programs under such collaboration. In addition, an acquirer could determine to reprioritize our collaborator's development programs such that our collaborator ceases to diligently pursue the development of our programs, and/or terminates its collaboration with us. Genentech is a wholly-owned member of the Roche Group and as such is subject to the risk that Roche could determine to reprioritize Genentech's development programs which could reduce Genentech's efforts on the development or commercialization of Erivedge or cause Genentech to terminate our collaboration.

Genentech or Debiopharm may, under specified circumstances, terminate its collaboration 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 and financial communities.

Both Genentech and Debiopharm have the first right to maintain or defend our intellectual property rights under their respective agreements and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators' acts or omissions.

Genentech or Debiopharm 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.

Genentech or Debiopharm may not comply with all applicable regulatory requirements, may select clinical investigators who are not qualified or who fail to comply with protocols or applicable regulatory requirements, or may fail to report safety data in accordance with all applicable regulatory requirements.



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If either Genentech or Debiopharm were to breach or terminate its arrangement with us, the development and commercialization of the affected drug candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the drug candidate on our own.

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Either Genentech or Debiopharm may not have sufficient resources necessary to advance clinical development of drug candidates under our collaborations with each of them or may not obtain the necessary regulatory approvals.

If Genentech or Debiopharm fails to successfully develop and commercialize our drug candidates under collaboration, we may not be able to develop and commercialize these candidates independently or successfully enter into one or more alternative collaborations, in which event our financial condition, results of operations and stock price may be adversely affected.

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

Our current strategy is to seek corporate collaborators or licensees for the further development and commercialization of one or more of our targeted drug candidates, generally following our completion of at least phase I or phase II clinical testing. For example, while we are not presently seeking to enter into corporate collaborations for any of our proprietary programs, we are likely to seek to partner CUDC-427, CUDC-907, and CUDC-101 as well as other drug candidates that we may develop internally or acquire from third parties in the future. We do not currently have the resources or capacity to advance these programs into later stage clinical development (i.e., phase III) or commercialization on our own. As such, our success will depend, in part, on our ability to enter into one or more such collaborations. We face significant competition in seeking appropriate collaborators and a number of recent business combinations among large pharmaceutical companies have resulted 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 for CUDC-427, CUDC-907, CUDC-101 or any future programs 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 sufficient differentiability compared to existing or emerging treatments. 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 strategic partnerships 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;

we will 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.

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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. 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;

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 study participants may result in increased costs, program delays or program termination;

our products under development may not be effective in treating any of the projected cancer indications 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 GCPs 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 FDA's or foreign equivalent's review or approval of our products, or the rejection of data developed with the involvement of such

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person(s) or institution(s).

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;

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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. 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 may result in increased development costs for our drug candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

**We expect to 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. Our reliance on these third parties for clinical development activities will reduce our control over these activities. 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 and our collaborative partners do not obtain, or if there are delays in obtaining, necessary regulatory approvals, then we will not be able to commercialize our drug candidates and our business will be materially impaired and the market price of our common stock could substantially decline.**

We and our collaborators 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

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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 our collaborators 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 any collaborative partners 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 any collaborators 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 any collaborators incur costs and delays in 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.

**Even if marketing approval is obtained, any products we or any collaborators develop will be subject to ongoing regulatory oversight, which may affect the successful commercialization of such products.**

Even if we or any collaborators obtain regulatory approval of a drug candidate, the approval may be subject to limitations on the approved indicated uses for which the product can be marketed, require labeling that highlights undesirable safety risks, impose restrictions on how the product can be distributed and used pursuant to a REMS, or require costly post-marketing follow-up studies. After marketing approval for any product is obtained, the manufacturer and the manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA, or its foreign equivalent, and other regulatory agencies. The subsequent discovery of previously unknown problems with the product, or with the manufacturer or facility, or a failure to comply with regulatory requirements, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market, fines, refusal to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, refusal to permit the import or export of our products or those of our collaborators, and criminal prosecution.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our or our collaborators' drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we or they may lose any marketing approvals that have been obtained, which would adversely affect the amount of revenue generated from such products and adversely affect our ability to achieve or sustain profitability.

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In addition to regulations imposed by the FDA or foreign equivalents, we and our current collaborators are, and any potential future collaborators will be, subject to regulation under, among other laws, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, as well as regulations administered by the Nuclear Regulatory Commission, national restrictions on technology transfer, import, export and customs regulations and certain other local, state or federal regulations. From time to time, other federal agencies and congressional committees have indicated an interest in implementing further regulation of pharmaceutical and biotechnology companies. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we or any collaborators would be able to comply with any applicable regulations. Failure to comply with regulatory requirements, may result in actions such as:

restrictions on such products, manufacturers or manufacturing processes;

restrictions on the marketing of a product;

restrictions on product distribution;

requirements to conduct post-marketing clinical trials;

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 potential future relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.**

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our potential 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 our products for which we obtain marketing approval. Restrictions under applicable federal and

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state healthcare laws and regulations, include the following:

the federal healthcare anti-kickback statute 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 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 federally funded healthcare programs such as Medicare and Medicaid;

the federal False Claims Act imposes 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, 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, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including



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mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

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

the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, or the PPACA requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

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

**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, 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;

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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.

If we or our collaborators are not able to obtain market acceptance for such products, our expected revenues from sales of these products would be adversely affected and our business may not be successful.

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**RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS**

**We and our collaborators may not achieve projected research and development 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 and potential regulatory approval of Erivedge in territories other than the U.S., and may in the future make additional statements about its goals and expectations for this 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 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 or receive regulatory approvals 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 the above research and development 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 pathway. We believe that there are currently at least five other companies that have progressed Hedgehog pathway inhibitors into clinical development: Eli Lilly and Company, Exelixis, Inc. (in co-development with the Bristol-Myers Squibb Company); Pfizer Inc.; Novartis International AG; and Millennium Pharmaceuticals.

In addition, there are several companies developing drug candidates that target the same cancer pathways that we are targeting or that are testing drug candidates in the same cancer indications that we are testing. For example, Debiopharm SA, Novartis AG and Tetralogic, Inc. are all developing IAP inhibitors and several companies are investigating HSP90 inhibitors in clinical testing, including, among others Astex Therapeutics Ltd., Daiichi Sankyo, Esanex, Inc., Kyowa Hakko Kirin Co, Ltd., Novartis International AG, Samus Therapeutics, Inc. and Synta Pharmaceuticals Corp. There are commercially-available drugs that individually target either HDAC or EGFR as well as a drug that targets EGFR/Her2. There are also several drug candidates in clinical testing that are designed to inhibit one or more of these targets. However, we are not aware of other molecules in clinical testing that are designed to simultaneously target HDAC, EGFR and Her2 or HDAC and PI3K simultaneously.

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 life science, medical device

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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. 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 future products or result in reputational harm and could result in the payment of a significant damage award.

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.

**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, including Daniel R. Passeri, our Chief Executive Officer, Ali Fattaey, Ph.D., President and Chief Operating Officer, Maurizio Voi, M.D., our Chief Medical and Chief Development Officer, and Michael P. Gray, our Chief Financial Officer. 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 will depend 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.

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**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. For example, we licensed CUDC-427 from Genentech in November 2012 for payments totaling \$9,500,000. 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, which could impede our efforts in China and materially and adversely affect the development of our targeted cancer drug candidates.**

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 of our development efforts in China. If our research and development efforts in China are delayed due to such interruptions, 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 that is currently conducted in China to U.S. or European providers, thereby potentially either increasing our overall costs for such services or reducing the total number of chemists and or/biologists that we could engage. In addition, the Chinese legal system is a civil law system based on written statutes. Unlike common law systems, it is a system in which decided legal cases have little precedential value. Accordingly, we cannot predict the effect of future

developments in the Chinese legal system, including the

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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 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 generally accepted accounting principles, or 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 related disclosure. Such estimates and judgments include the carrying value of our property, 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, or 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 elsewhere in this Annual Report on Form 10-K.

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

Despite the implementation of security measures, our internal computer systems 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 could result in a material disruption of our product development programs. 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 the further development of our drug candidates may be delayed.

## **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





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in significant ways and are expected to continue to change. 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. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the U.S. and in many countries abroad are maintained in secrecy until 18 months after filing, it is possible that third parties have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our knowledge. The U.S. Congress recently passed the Leahy-Smith America Invents Act, or the America Invents Act, which reforms U.S. patent law in part by changing the standard for patent approval from a first to invent standard to a first to file standard and instituting a post-grant review system. This new legislation changes U.S. patent law in a way that may weaken our ability to obtain or maintain patent protection for future inventions in the U.S.

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 freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

**We may become involved in expensive and unpredictable patent litigation or other 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;

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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 infringe 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.

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

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

During the years ended December 31, 2012, 2011, and 2010, we 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. Implementation and enforcement of Chinese intellectual property-related laws has historically been inconsistent and damages assessed may fail to reflect the true value of the infringed technology and its market. Accordingly, 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 varies, 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.

**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. 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.

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**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 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 products under development, and if these third parties do not successfully formulate or manufacture these drug candidates, our business will be harmed.**

We have no manufacturing experience or manufacturing capabilities. In order to continue to develop drug candidates, apply for regulatory approvals, and commercialize our products under development, we or any collaborators must be able to manufacture products 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 or Quality System Regulation and other governmental regulations and corresponding foreign standards. Any failure by our or our collaborators' contract manufacturers, any 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

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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 that are 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 demands 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 were unable to purchase raw materials after regulatory approval had been obtained for our drug candidates, the commercial launch of our drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our drug candidates.

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

We have no sales, marketing or product distribution experience. 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 and Debiopharm, we have granted Genentech and Debiopharm the exclusive rights to distribute certain products resulting from such collaborations, and Genentech is currently distributing Erivedge as part of its U.S. commercialization rights following FDA approval of Erivedge in January 2012. We may have to enter into additional marketing 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 to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

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We may seek to independently market products that are not already subject to marketing 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.

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In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MPDIMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded

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Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MPDIMA applies only to drug 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 MPDIMA may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, which we refer to as the PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the PPACA revises the definition of average manufacturer price for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. Although it is too early to determine the full effect of the PPACA, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA and the MPDIMA may prevent us from maintaining prices for our approved drug candidates that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results. In addition, to the extent that our approved drug candidates, if any, are marketed outside of the U.S., foreign government pricing controls and other regulations may prevent us from maintaining prices for such products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results.

## **RISKS RELATED TO OUR COMMON STOCK**

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

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 \$1.97 per share for the period January 1, 2011 through March 6, 2013. 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 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 potential products;

actual or anticipated variations in our quarterly operating results, including Erivedge royalty revenue that we receive from Genentech, and any subsequent restatement of such results;

actual or anticipated changes to our research and development plans;

deviations in our operating results from the estimates of securities analysts;



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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 and warrants 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 warrants 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.

Furthermore, as of December 31, 2012, we have outstanding warrants to purchase 1,373,517 shares of our common stock that contain antidilution adjustment provisions that will result in a decrease in the price and an increase in the number of shares of common stock issuable upon exercise of such warrants in the event of certain issuances of common stock by us at prices below \$3.55 per share. For example, assuming that we issued and sold shares of common stock in a public offering at \$3.00 per share, these warrants would become exercisable for an aggregate of 1,389,757 shares of our common stock, at an exercise price of \$3.51 per share, which is equal to an aggregate of additional 16,240 shares as a result of the adjustment. To the extent that we are required to adjust the price and number of shares underlying these warrants as a result of this antidilution clause, and thereafter such warrants are exercised, additional shares of our common stock will be issued that will be eligible for resale in the public market, which could result in added dilution to our security holders and could also have an adverse effect on the market price of our common stock.

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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

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offerings at prices and terms to be determined at the time of sale. For example, in June 2011 we entered into the ATM Agreement with MLV pursuant to which, from time to time, we may offer and sell up to \$20 million of the common stock that was registered on this shelf registration statement through MLV pursuant to one or more at the market offerings. In addition, with our prior written approval, MLV may also 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.

**Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to devote substantial time to compliance initiatives, and if our independent registered public accounting firm is required to provide an attestation report on our internal controls but is unable to provide an unqualified attestation report, our stock price could be adversely affected.**

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on the effectiveness of our internal control over financial reporting. The internal control report must contain (i) a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting, (ii) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting and (iii) management's assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective.

To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, hire additional employees for our finance and audit functions, potentially engage outside consultants and adopt a detailed work plan to (i) assess and document the adequacy of internal control over financial reporting, (ii) continue steps to improve control processes where appropriate, (iii) validate through testing that controls are functioning as documented, and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. In addition, in connection with the attestation process by our independent registered public accounting firm, if required, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, investors could lose confidence in our financial information and our stock price could decline.

**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 December 31, 2012, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 36% 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

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discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

**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 our current management and the market price of our common stock may be lower as a result.**

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

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

### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

### **ITEM 2. PROPERTIES**

We currently lease a facility for our administrative, research and development requirements located at 4 Maguire Road in Lexington, Massachusetts consisting of 24,529 square feet pursuant to a lease that expires February 2018. We believe that our existing facility will be suitable and adequate to meet our needs for the foreseeable future.

### **ITEM 3. LEGAL PROCEEDINGS**

We are currently not a party to any material legal proceedings.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDERS MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

(a) *Market Information.* Our common stock is traded on the NASDAQ Global Market under the trading symbol CRIS. The following table sets forth, for the fiscal periods indicated, the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market:

	Curis Common Stock	
	High	Low
<b>Year ended December 31, 2011</b>		
First Quarter	\$ 3.63	\$ 1.97
Second Quarter	\$ 4.42	\$ 3.00
Third Quarter	\$ 4.30	\$ 2.70
Fourth Quarter	\$ 4.72	\$ 2.87
<b>Year ended December 31, 2012</b>		
First Quarter	\$ 5.65	\$ 4.20
Second Quarter	\$ 5.49	\$ 4.40
Third Quarter	\$ 5.51	\$ 3.83
Fourth Quarter	\$ 4.27	\$ 2.98

(b) *Holders.* On March 6, 2013, the last reported sale price of our common stock on the NASDAQ Global Market was \$3.24 and there were 241 holders of record of our common stock. The number of record holders may not be representative of the number of beneficial owners because many of the shares of our common stock are held by depositories, brokers or other nominees.

(c) *Dividends.* We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, to support our business strategy and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the sole discretion of our board of directors after taking into account various factors, including our financial condition, operating results, capital requirements and any plans for expansion.

(d) *Issuer Purchases of Equity Securities.* We did not make any purchases of our shares of common stock in 2012.

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(e) *Performance Graph.* The graph below compares the cumulative total stockholder return on our common stock for the period from December 31, 2007 through December 31, 2012, with the cumulative total return on (i) NASDAQ Pharmaceutical Index , (ii) NASDAQ Composite Index and (iii) NASDAQ Biotechnology Index. The comparison assumes investment of \$100 on December 31, 2007 in our common stock and in each of the indices and, in each case, assumes reinvestment of all dividends.

	12/31/07	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12
CURIS INC.	100.00	76.53	331.63	202.04	477.55	350.00
NASDAQ COMPOSITE INDEX	100.00	59.03	82.25	97.32	98.63	110.78
NASDAQ PHARMACEUTICAL INDEX	100.00	97.45	104.75	111.47	123.06	164.89
NASDAQ BIOTECHNOLOGY INDEX	100.00	93.40	103.19	113.89	129.12	163.33

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The selected consolidated financial data set forth below have been derived from our consolidated financial statements. These historical results are not necessarily indicative of results to be expected for any future period. You should read the data set forth below in conjunction with

Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes included elsewhere in this report.

	Year Ended December 31,				
	2012	2011	2010	2009	2008
(in thousands, except per share data)					
<b>Consolidated Statement of Operations and Comprehensive Loss Data:</b>					
Revenues:					
License and maintenance fees(1)	\$ 14,000	\$ 14,300	\$ 15,656	\$ 7,809	\$ 7,853
Royalties	1,530				
Research and development(2)	1,442	463	344	781	514
Net revenues	16,972	14,763	16,000	8,590	8,367
Costs and expenses:					
Cost of royalty revenues	176				
Research and development.	15,493	13,693	11,373	9,933	13,226
In-process research and development.	9,500				
General and administrative.	10,423	8,273	10,265	8,702	8,260
Total costs and expenses	35,592	21,966	21,638	18,635	21,486
Loss from operations	(18,620)	(7,203)	(5,638)	(10,045)	(13,119)
Other income (expense):					
Interest and other income	150	100	627	222	1,000
Interest expense	(204)				(4)
Change in fair value of warrants	2,257	(2,756)	576		
Total other income (expenses), net	2,203	(2,656)	1,203	222	996
Net loss	\$ (16,417)	\$ (9,859)	\$ (4,435)	\$ (9,823)	\$ (12,123)
Basic and diluted net loss per common share	\$ (0.21)	\$ (0.13)	\$ (0.06)	\$ (0.15)	\$ (0.19)
Weighted average common shares (basic and diluted)	79,059	76,352	74,959	65,061	63,378

	(in thousands)				
	As of December 31,				
	2012	2011	2010	2009	2008
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investments	\$ 58,701	\$ 37,718	\$ 40,380	\$ 25,035	\$ 28,853
Working capital	52,873	34,717	37,608	23,347	26,748
Investment restricted	194	236	497	216	210
Total assets	69,768	48,180	50,649	36,099	39,982
Long-term obligations(3)	31,522	4,518	1,656		
Accumulated deficit	(748,505)	(732,088)	(722,229)	(717,793)	(707,971)
Total stockholders' equity	34,267	39,876	45,518	33,052	37,225

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- (1) During the years ended December 31, 2012, 2011, 2009 and 2008, we recognized \$14,000,000, \$14,000,000, \$6,000,000 and \$6,000,000 of revenue for cash payments that we earned during each of 2012,



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2011, 2009 and 2008, respectively, under our June 2003 Hedgehog pathway inhibitor collaboration with Genentech. During the year ended December 31, 2010, we recognized \$11,000,000 of revenue for cash payments that we earned under our August 2009 license agreement with Debiopharm, and we also recognized \$4,000,000 in settlement proceeds from Micromet pursuant to the settlement agreement that we entered into in February 2010 to resolve a contract claim we filed related to our June 2001 agreement with Micromet.

- (2) During the year ended December 31, 2012, we recognized \$1,000,000 of research and development revenue for milestones that we earned under our November 2011 agreement with LLS.
  
- (3) Long-term obligations for the year ended December 31, 2012 relates to long-term debt associated with our Erivedge royalty financing transaction entered into in December 2012 of \$30,000,000, and a warrant liability established as part of our January 2010 registered direct offering of \$1,488,000 with the remainder related to deferred rent payments. Long-term obligations for the years ended December 31, 2011 and 2010 are comprised of a warrant liability established as part of our January 2010 registered direct offering of \$4,361,000 and \$1,605,000, respectively, with the remainder related to deferred rent payments.

**Table of Contents****ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis of financial condition and results of operations should be read together with Selected Financial Data, and our financial statements and accompanying notes appearing elsewhere in this annual report on Form 10-K. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under Item 1A, Risk Factors and elsewhere in this report.*

**Overview**

We are an oncology-focused company seeking to develop and commercialize next generation targeted drug candidates for cancer treatment. We conduct our research and development programs both internally and through strategic collaborations. Erivedge® is the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma, and was developed and is being commercialized by Roche and Genentech under a collaboration agreement between Curis and Genentech. We are also leveraging our experience in targeting signaling pathways to develop clinical-stage targeted cancer programs, including CUDC-427, a small molecule IAP inhibitor, CUDC-907, a dual PI3K and HDAC inhibitor and CUDC-101, an EGFR, Her2 and HDAC inhibitor. Our licensee Debiopharm is progressing the clinical development of HSP90 inhibitor, Debio 0932.

**Erivedge®**

*Erivedge® (vismodegib) capsule.* Our most advanced program is a Hedgehog pathway inhibitor program under collaboration with Genentech. Pursuant to this collaboration, Genentech and Roche are responsible for clinical development, and Genentech (in the U.S.), Roche (outside the U.S., excluding Japan) and Chugai (in Japan) are responsible for commercialization of Erivedge.

In January 2012, the FDA approved the Erivedge capsule for treatment of adults with BCC that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. We refer to this indication as advanced BCC. Erivedge is also the subject of regulatory reviews for potential approval in advanced BCC by several health authorities outside of the U.S., including in Europe and Australia. In addition, Genentech is testing Erivedge in clinical trials to treat less severe forms of BCC. Third-party investigators are also conducting clinical trials with Erivedge in BCC as well as in several other cancers.

As a result of the FDA's approval of Erivedge for advanced BCC, we earned a \$10,000,000 payment from Genentech, which we recognized as license revenue during the year ended December 31, 2012. In addition, we recorded research and development expenses related to the FDA's approval of Erivedge of \$1,464,000 during this same period which represents our obligations to university licensors. Of this amount, \$964,000 represents the fair value of a one-time issuance of an aggregate of 200,000 shares of our common stock to two university licensors in connection with the FDA approval of Erivedge. The remaining \$500,000 represents sublicense fees we paid to these same university licensors upon our receipt of the \$10,000,000 milestone payment.

In May 2012, we earned a \$4,000,000 milestone payment in connection with Roche's filing of an application for marketing registration for Erivedge with Australia's TGA, which we also recognized as license revenue during the year ended December 31, 2012. During the fourth quarter of 2011, Roche submitted an MAA for Erivedge to the EMA, for which we earned a \$6,000,000 milestone payment. In addition, we made cash payments of \$950,000 which represents our obligations to university licensors. Of this amount, \$450,000 represents one-time cash milestones specific to the Australian territory and the remaining \$500,000 represents ongoing sublicense fees totaling 5% of the \$10,000,000 in milestone payments that we received from Genentech. As a result of these payments, we recognized expenses of \$650,000 and \$300,000 during the years ended December 31, 2012 and 2011, respectively.

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Roche has indicated that it anticipates potential EMA approval for Erivedge during the first half of 2013. Roche also filed new drug applications in 2012 for marketing registration with health agencies in other territories seeking approval for Erivedge in advanced BCC. Erivedge's FDA approval and Roche's regulatory submissions in regards to Erivedge in Europe, Australia, and other territories are based on positive clinical data from ERIVANCE BCC/SHH4476g, a pivotal phase II study of Erivedge in patients with advanced BCC. We will receive additional milestone payments if Erivedge receives EMA or TGA marketing authorization and will be obligated to make payments to university licensors that total 5% of each of these milestone payments that we receive.

Pursuant to the terms of our collaboration agreement with Genentech, we are entitled to a royalty on net sales of Erivedge that ranges from the mid-to-high single digits, and which escalates within this range with increasing product sales. The royalty rate applicable to Erivedge may be decreased to a low-to-mid single digit royalty 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. In December 2012, through our wholly-owned subsidiary Curis Royalty, we entered into a \$30,000,000 debt transaction with BioPharma-II. The debt is secured with certain future royalties of Erivedge®. Pursuant to the terms of the credit agreement, Curis Royalty borrowed \$30,000,000 at an annual interest rate of 12.25% and upon closing, we transferred to Curis Royalty the right to receive certain royalty and royalty-related payments from the commercial sales of Erivedge under Curis' collaboration agreement with Genentech.

The loan from BioPharma-II will be repaid by Curis Royalty from the proceeds of the royalty and royalty-related payments that it receives from time to time from Genentech. Quarterly royalty and royalty-related payments from Genentech will first be applied to pay (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis royalty obligations to university licensors, as described below, (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 \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$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 and distribute to Curis remaining royalty and royalty-related amounts in excess of the foregoing caps, if any. In addition, if Erivedge royalties are insufficient to pay the accrued interest on the outstanding loan, unpaid interest will be added to the principal on a quarterly basis. As a result, we will continue to record royalty revenue from Genentech but expect the majority, if not all, of such revenues, subject to the above caps, will be used to pay down the loan received from BioPharma-II.

We are also obligated to make payments to university licensors on royalties that we earn in all territories other than Australia in an amount that 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 we would earn from Roche's potential future sales of Erivedge in Australia, we will be obligated to make payments to university licensors in an amount that is equal to 2% of Roche's direct net sales in Australia until April 2019, after which the amount will decrease to 5% of the royalty payments that we receive from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022.

We recognized \$1,530,000 of royalty revenue from Genentech's net sales of Erivedge during the year ended December 31, 2012, which was calculated as 5% of Genentech's net sales of Erivedge. We recorded cost of royalty revenues of \$176,000 during this same period, including a \$100,000 one-time cash payment paid to a university licensor upon the first commercial sale of Erivedge and \$76,000 paid to two university licensors, which represents 5% of the royalties that we earned with respect to Erivedge during the year ended December 31, 2012.

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***Targeted Cancer Drug Candidates***

*CUDC-427.* IAP proteins are a family of functionally and structurally related proteins that promote cancer cell survival inhibiting apoptosis. Using IAP proteins and other anti-apoptotic factors, cancer cells evade apoptosis in response to a variety of signals, including those provided by anti-cancer agents such as chemotherapy, or naturally occurring inflammatory and immune signals transmitted through members of tumor necrosis factor, or TNF family of factors. Evasion from apoptosis is a fundamental mechanism whereby human cancers develop resistance to standard anti-cancer treatments. IAP inhibitors such as CUDC-427 are designed to counteract the effects of IAP proteins, thus shifting the balance away from cancer cell survival and allowing apoptosis to proceed.

In November 2012, we licensed from Genentech the exclusive, worldwide rights for the development and commercialization of a small molecule drug candidate, CUDC-427, that is designed to promote cancer cell death by antagonizing IAP proteins. 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. During the fourth quarter of 2012, we incurred in-process research and development expenses of \$9,500,000, representing the up-front license payment and technology transfer costs payable to Genentech. In addition, Genentech will be entitled to receive milestone payments upon the first commercial sale of CUDC-427 in certain territories and a tiered single-digit royalty on net sales of CUDC-427, if any.

Prior to our license, Genentech had completed enrollment in a phase I clinical trial of CUDC-427, previously named GDC-0917, in which 42 patients received daily oral doses of CUDC-427 for two weeks, followed by a one week rest period until disease progression or study discontinuation for any other reason. Genentech plans to present full study results at a medical conference in mid-2013. We plan to continue the further clinical development of CUDC-427 and to initiate additional clinical studies in 2013.

*CUDC-907.* CUDC-907 is an orally bioavailable, network-targeted small molecule drug candidate designed and discovered by us to inhibit PI3K and HDAC enzymes. In November 2011, we entered into an agreement under which LLS will provide up to \$4 million in milestone payments to support our ongoing development of CUDC-907. In January 2013, we treated the first patient in a Phase I clinical trial in patients with advanced lymphoma and multiple myeloma and as of March 6, 2013, the first cohort of 3 patients has been enrolled in this study. As of March 6, 2013, we have earned \$1,100,000 in milestone payments under the terms of the agreement with LLS.

*CUDC-101.* CUDC-101 is a drug candidate that is designed to target EGFR/Her2 and HDAC. To date, we have completed two clinical trials with an intravenous formulation of CUDC-101, including a phase I dose escalation clinical trial of CUDC-101 in 25 patients with advanced, refractory solid tumors and a phase I expansion trial that tested CUDC-101 in 46 patients with specific tumor types, including breast, gastric, head and neck, NSCLC or liver cancers. An intravenous formulation of CUDC-101 is currently being tested in a phase I clinical trial in patients with locally advanced squamous cell carcinoma of the head and neck in combination with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation. We have enrolled ten patients in this trial as of March 6, 2013.

In October 2012, we initiated a phase I clinical trial of an oral formulation of CUDC-101. We subsequently terminated this study as the bioavailability observed in the first cohort of patients too low to achieve effective drug levels with this formulation. We are currently pursuing the development of alternative formulations that may provide improved oral bioavailability, as well as backup molecules whose chemical properties may be more amenable to the oral route of administration.

*Debio 0932.* 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 has assumed all future development responsibility for Debio 0932 and Debiopharm or a Debiopharm licensee will incur all future costs related to the development, registration and commercialization of products under the agreement.

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In April 2010, Debiopharm initiated a phase I clinical trial to evaluate the safety of Debio 0932 in patients with advanced solid tumors. In 2011, Debiopharm successfully advanced Debio 0932 through the dose escalation portion of this phase I study and presented results of this study at the annual meeting of the American Society of Clinical Oncology in June 2012. In August 2012, Debiopharm initiated the HSP90 inhibition and lung cancer outcomes study, or HALO, a phase I-II clinical trial of the safety and efficacy of Debio 0932 in combination with standard of care first- and second-line chemotherapy agents in patients with advanced, stage IIIb or IV NSCLC, that is characterized as wild-type EGFR. In addition, Debiopharm has recently indicated that it plans to initiate another Phase I study in patients with renal cell carcinoma during the second half of 2013. We are eligible for contingent payments upon treatment of the fifth patient in each of these phase II studies if Debio 0932 progresses to this stage.

### ***Liquidity***

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our corporate collaborators, the private and public placement 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 \$748,505,000 as of December 31, 2012. We expect that we will incur significant operating losses for the next several years as we seek to advance our research and development programs. Although Genentech recently received FDA approval to market Erivedge in the U.S., the level of future sales and the amount of resulting royalty revenue payable to us are both highly uncertain. In addition, in December 2012 we entered into a \$30,000,000 debt financing that is secured by Erivedge royalty revenues and for which up to \$4,000,000, \$8,000,000 and \$12,000,000 of our royalty revenues in 2013, 2014 and 2015 are required to be applied to debt repayments. For years after 2015, all royalty revenues that we receive will be applied to debt repayment until the debt is fully repaid. We currently estimate that the debt will be repaid by early 2017, but the actual timing of repayment will be dependent on the amount of royalty revenues that we earn on sales of Erivedge.

We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. As a result of uncertainty in the amounts of future Erivedge royalty revenue and the period that will be required to repay the royalty-secured debt obligation, the timing of potential milestone payments under our agreements with Genentech, Debiopharm and LLS and the variability in our operating expenses, we expect that our financial results in the future will be variable. We anticipate that existing capital resources as of December 31, 2012 should enable us to maintain current and planned operations into mid-2015. Our ability to continue funding our planned operations into and beyond mid-2015 is dependent on future contingent payments that we may receive from Genentech, Debiopharm, or LLS upon the achievement of development and regulatory approval objectives, our ability to manage our expenses and our ability to raise additional funds through additional corporate collaborations, equity or debt financings, or from other sources of financing.

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

Genentech's ability to successfully scale up the commercialization of Erivedge in advanced BCC in the U.S.;

Genentech's and/or Roche's receipt of approval to commercialize Erivedge in advanced BCC in Europe and other territories including in Australia as well as its ability to successfully launch and commercialize Erivedge in these markets;

positive results in Genentech's ongoing phase II clinical trial in patients with operable BCC;

our ability to successfully plan, finance and complete current and planned clinical trials for CUDC-427, CUDC-907 and CUDC-101 and advance each drug candidate into phase II clinical testing;

Debiopharm's ability to advance Debio 0932 into later stages of clinical development; and

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our ability to successfully enter into one or more material licenses or collaboration agreements for our proprietary drug candidates. 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 commercialize drugs other than Erivedge based upon our proprietary technologies.

Our current collaboration and license agreements are summarized as follows:

*Genentech Hedgehog Pathway Inhibitor Collaboration.* Under the terms of the June 2003 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 pathway inhibitors. Genentech subsequently granted a sublicense to Roche for non-U.S. rights to GDC-0449, 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 not a party to this agreement between Genentech and Roche but we are eligible to receive cash payments for regulatory filing and approval objectives achieved and future royalties on products developed outside of the U.S., if any, under our June 2003 collaboration agreement with Genentech.

The lead drug candidate being developed under this program is Erivedge, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor that is the first and only FDA-approved medicine for adults with advanced forms of basal cell carcinoma. Genentech and Roche are responsible for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing of Erivedge. We are eligible to receive cash payments for regulatory filing and approval objectives achieved and future royalties on products developed outside of the U.S., if any, under our June 2003 collaboration agreement with Genentech. 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 \$46,000,000 to date. We are also eligible to receive royalties on sales of any Hedgehog pathway inhibitor products that are successfully commercialized by Genentech and Roche, for which we recognized \$1,530,000 in such revenue for sales of Erivedge during the year ended December 31, 2012. Future royalty payments related to Erivedge will service the outstanding debt and accrued interest to BioPharma-II, up to the quarterly caps for 2013, 2014 and 2015, and until the debt is fully repaid thereafter.

*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 have the sole right and responsibility for all research, development, manufacturing and commercialization activities related to CUDC-427. During the fourth quarter of 2012, we incurred expenses of \$9,500,000 representing an up-front license payment and technology transfer costs payable to Genentech. In addition, 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.

*The Leukemia & Lymphoma Society Agreement.* In November 2011, we entered into an agreement with LLS, under which LLS will provide approximately 50% of the direct costs of the development of CUDC-907, up to \$4,000,000, through milestone payments upon our achievement of specified development objectives with CUDC-907, in patients with relapsed or refractory lymphomas and multiple myeloma. In the fourth quarter of 2012, we earned milestone payments of \$1,000,000 under the terms of the agreement with LLS related to CUDC-907. We will be obligated to make future contingent payments, including potential royalty payments under our agreement with LLS upon our successful entry into a partnering agreement for CUDC-907 or upon the achievement of regulatory and commercial objectives, with such payments being limited to a maximum of 2.5 times the actual milestone payments that we receive from LLS under this agreement.

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*Debiopharm HSP90 Collaboration.* In August 2009, we granted a worldwide, exclusive royalty-bearing license to our HSP90 inhibitor technology to Debiopharm. The lead molecule under this license collaboration was designated Debio 0932 by Debiopharm. Debiopharm has assumed all future development responsibility and costs related to the development, registration and commercialization of products under the agreement. As part of the consideration under the agreement, Debiopharm paid us an up-front license fee of \$2,000,000, and we received \$11,000,000 during 2010 in payments upon Debiopharm's successful achievement of clinical and regulatory objectives, including the approval from French regulatory authorities of Debiopharm's clinical trial application, or CTA, to begin phase I clinical trials and the treatment of the fifth patient in this trial. We are also eligible to receive royalties if any products under the license agreement are successfully developed and commercialized. For net sales of Debio 0932 that are made directly by Debiopharm, we are entitled to a high single-digit to low double-digit royalty, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to Debio 0932 may be reduced. We believe that it is more likely that Debiopharm will sublicense Debio 0932 following its further development, and in this case we are entitled to a share of royalties that Debiopharm receives from such sublicensee.

### **Financial Operations Overview**

*General.* Our future operating results will largely depend on the magnitude of payments from our current and potential future corporate collaborators and the progress of drug candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of our entry into new collaborations, if any, the timing of the receipt of payments, if any, from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being conducted. We anticipate that existing capital resources as of December 31, 2012 should enable us to maintain current and planned operations into mid-2015.

We expect to end 2013 with cash, cash equivalents, marketable securities and investments of \$31 million to \$36 million, excluding any potential payments from existing or new collaborators. We expect that our expenses associated with the clinical development will increase as we continue to treat patients in our phase I trials for CUDC-907 and CUDC-101 in head and neck cancers and initiate additional trials for CUDC-427 and CUDC-907, resulting in an increase in our research and development expenses for future periods as compared to prior years. We expect that research and development expenses for the year ended December 31, 2013 will be \$16 million to \$20 million and that general and administrative expenses will be \$10 million to \$12 million. These expense estimates include \$800,000 and \$1.9 million of stock-based compensation expense for research and development and general and administrative expense, respectively, which includes employee and director equity grants issued in January and February 2013. Actual stock-based compensation expense for fiscal 2013 may be higher as the result of our issuance of additional awards as part of our planned compensation programs, consistent with past practices.

*Debt.* In December 2012, through our wholly-owned subsidiary Curis Royalty, we entered into a \$30,000,000 debt transaction with BioPharma-II. The debt is secured with certain future royalties of Erivedge®. Pursuant to the terms of the credit agreement, Curis Royalty borrowed \$30,000,000 at an annual interest rate of 12.25% and upon closing, we transferred to Curis Royalty the right to receive certain royalty and royalty-related payments from the commercial sales of Erivedge under Curis' collaboration agreement with Genentech.

The royalty and royalty-related payments that Curis Royalty will be entitled to receive under the collaboration agreement with Genentech will be the source of funds to repay principal of and interest on the loan. The final maturity date of the loan will be the earlier of the date when principal is paid in full and the termination of Curis Royalty's right to receive royalties under the collaboration agreement with Genentech. The loan is secured by a security interest granted by Curis Royalty in its rights to receive royalty and other royalty-related payments under the collaboration agreement with Genentech. The loan constitutes an obligation of Curis Royalty and is non-recourse to Curis.

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Under the terms of the loan, quarterly royalty and royalty-related payments 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 \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$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 and distribute to Curis the remaining amounts above the caps, if any. Curis Royalty remains entitled to receive any royalty payments related to sales of Erivedge following repayment of the loan. Since the loan requires that up to \$4,000,000, \$8,000,000 and \$12,000,000 in royalty revenues are applied to pay interest and principal on the loan in 2013, 2014 and 2015, respectively, only royalty revenue in excess of these amounts, if any, will be available to fund our operations. No royalty revenues will be available for our use after 2015 until the loan is fully paid.

Per 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 transaction document proves 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 these conditions 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 might lose our right to royalty and royalty-related payments not transferred to BioPharma-II, including those we would otherwise be entitled to receive if, or when, Curis Royalty satisfied its obligations to BioPharma-II under the credit agreement.



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*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

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royalty payments. For the year ended December 31, 2012, milestone and royalty payments from Genentech accounted for \$15,893,000, or 94%, of our total revenue, all of which related to the development and commercialization of Erivedge. Since the first quarter of 2012, we have recognized royalty revenues related to Genentech's sales of Erivedge in the U.S. We expect to recognize royalty revenue in future quarters from Genentech's sales of Erivedge in the U.S. and in other markets where Genentech and Roche successfully obtain marketing approval, if any. Future royalty payments will service the outstanding debt and accrued interest to BioPharma-II, up to the quarterly caps for 2013, 2014 and 2015, and until the debt is fully repaid thereafter. We currently estimate that the debt will be repaid in early 2017.

We could receive additional milestone payments from Genentech, Debiopharm, and LLS, provided the respective programs meet contractually-specified development and regulatory objectives. For example, we earned a \$10,000,000 milestone payment from Genentech in January 2012 upon FDA approval of Erivedge and a \$4,000,000 milestone payment in May 2012 upon Roche's submission with Australian health authorities seeking to commercialize Erivedge in advanced BCC in Australia. Erivedge is currently being reviewed for potential marketing approval by European and Australian health authorities, as well as by health authorities in several additional territories. We are eligible to receive additional milestone revenue should Erivedge receive approval by European and/or Australian health authorities, and we are also eligible to receive royalties on net sales of Erivedge in all territories where Erivedge is sold.

We currently receive no research funding for our programs under our collaborations with Genentech, Debiopharm, and LLS and we do not expect to receive such funding in the future under these collaborations. Accordingly, our only source of revenues and/or cash flows from operations for the foreseeable future will be up-front license payments and funded research and development that we may receive under new collaboration agreements, if any, contingent cash payments for the achievement of clinical development and regulatory objectives, if any are met, under new collaborations or our existing collaborations with Genentech, Debiopharm, and LLS and royalty payments that are contingent upon the successful commercialization of any products based upon these collaborations. Our ability to enter into new collaborations and our receipt of additional payments under our existing collaborations with Genentech, Debiopharm, and LLS 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. These costs currently consist of payments we are obligated to make to university licensors on royalties that we earn 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 we would earn from Roche's future sales of Erivedge in Australia, if such approval is received, we will be obligated to make payments to university licensors in an amount that is equal to 2% of Roche's direct net sales in Australia until April 2019, after which the amount will decrease to 5% of the royalty payments that we receive 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 discover, research and develop our drug candidates. These expenses consist primarily of: (1) salaries and related expenses for personnel including stock-based compensation expense; (2) outside service costs including, clinical research organizations and medicinal chemistry; (3) sublicense payments; and (4) the costs of supplies and reagents, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. We are currently incurring research and development expenses under our Hedgehog 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 earning payments from Genentech related to the achievement of clinical development and regulatory objectives under our Hedgehog pathway inhibitor collaboration.

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Our development programs, both internal and under collaboration, are summarized in the following table:

<b>Drug candidate</b>	<b>Primary Disease</b>	<b>Collaborator/Licensee</b>	<b>Status</b>
<b><i>Hedgehog Pathway Inhibitor</i></b> - Erivedge	Advanced BCC	Genentech	FDA approved;
- Erivedge	Operable Nodular BCC	Genentech	Regulatory submissions pending in EU, Australia and other territories Phase II
<b><i>Antagonist of IAP Proteins</i></b> - CUDC-427	Breast cancer and other solid tumors and hematological cancers	Internal development	Completed Phase I
<b><i>Dual PI3K and HDAC Inhibitor</i></b> - CUDC-907	Advanced lymphomas and multiple myeloma	Internal development/LLS	Phase I
<b><i>EGFR/HER2 and HDAC Inhibitor</i></b> - CUDC-101 intravenous formulation	Locally advanced SCCHN	Internal development	Phase I
<b><i>HSP90 Inhibitor</i></b> - Debio 0932	Advanced NSCLC	Debiopharm	Phase I/II
- Debio 0932	Solid tumor cancers	Debiopharm	Phase Ib

Because of the early stages of development of these programs, our ability and that of our collaborators and licensees to successfully complete preclinical studies and clinical trials of these drug candidates, and the timing of completion of such programs, is highly uncertain. There are numerous risks and uncertainties associated with developing drugs which may affect our and our collaborators' future results, including:

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

the results of future preclinical studies and clinical trials;

the cost and timing of regulatory approvals;

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 I, Item 1A Risk Factors.

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*In-process Research and Development.* We recognized in-process research and development expenses of \$9,500,000 during the year ended December 31, 2012 for to the one-time license and technology transfer fees related to the licensing of CUDC-427 from Genentech.

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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 may increase in future periods as compared to prior periods as patent costs related to our proprietary programs and Hedgehog pathway inhibitor collaboration with Genentech could increase, as well as an increase in employee-related costs associated with additions to our senior management team.

### **Critical Accounting Policies and Estimates**

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

While our significant accounting policies are more fully described in our consolidated financial statements, we believe that the following accounting policies are critical to understanding the judgments and estimates we use in preparing our financial statements:

#### ***Revenue Recognition***

Our business strategy includes entering into strategic license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of our drug candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development milestones and royalties on product sales. We follow the provisions of the Financial Accounting Standards Board, or FASB, Codification Topic 605, *Revenue Recognition*.

#### ***License Fees and Multiple Element Arrangements.***

In January 2011, we adopted a new U.S. GAAP accounting standard which amends existing revenue recognition accounting guidance to provide accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This new guidance eliminates the requirement to establish objective evidence of fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no vendor-specific objective evidence or third-party evidence to determine the fair value of that undelivered item. The new standard was implemented on a prospective basis for new or materially modified arrangements beginning in 2011.

For multiple element arrangements, including license agreements, entered into prior to January 1, 2010, guidance required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under this guidance, if the fair value of all of the undelivered elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined.

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Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with U.S. generally accepted accounting principles, or GAAP. We recognize up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations, typically including research and/or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. We recognize revenue using the relative performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance. Revenue recognized under the relative performance method would be determined by multiplying the total payments under the contract, excluding royalties and payments contingent upon achievement of substantive milestones, by the ratio of level of effort incurred to date to estimated total level of effort required to complete our performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement, the performance obligations are provided on a best-efforts basis and we can reasonably estimate when the performance obligation ceases or becomes inconsequential, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential and perfunctory. Revenue is then recognized over the remaining estimated period of performance.

In addition, if we are involved in a steering committee as part of a multiple element arrangement that is accounted for as a single unit of accounting, we assess whether our involvement constitutes a performance obligation or a right to participate. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which we expect to complete our aggregate performance obligations.

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*Substantive Milestone Payments.* Our collaboration agreements may also contain substantive milestone payments. Collaboration agreements that contain substantive milestone payments are recognized upon achievement of the milestone only if:

such milestone is commensurate with either of the following:

- a) the vendor's performance to achieve the milestone (for example, the achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement); or
- b) the enhancement of the value of the deliverable as a result of a specific outcome resulting from the vendor's performance to achieve the milestone (or substantive effort on our part is involved in achieving the milestone);

such milestone relates solely to past performance; and

the amount of the milestone payment is reasonable relative to all deliverables and payment terms in the arrangement. Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above. In addition, the determination that one such payment was not a substantive milestone could prevent us from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable. Milestones that are tied to regulatory approval are not considered probable of being achieved until such approval is received. Milestones tied to counter-party performance are not included in our revenue model until the performance conditions are met.

*Reimbursement of Costs.* Reimbursement of research and development costs by third party collaborators are recognized as revenue provided the provisions of the FASB Codification Topic 605-45, *Revenue Recognition, Principal Agent Consideration*, are met, the amounts are determinable, and collection of the related receivable is reasonably assured.

*Royalty Revenue.* Since the first quarter of 2012, we have recognized royalty revenues related to Genentech's sales of Erivedge in the U.S. We expect to recognize royalty revenue in future quarters from Genentech's sales of Erivedge in the U.S. and in other markets where Genentech and Roche successfully obtain marketing approval, if any. However, Erivedge royalties we earn will service our debt to BioPharma-II, and only amounts in excess of certain quarterly repayment caps, if any, will be available to us for use in operations. Royalty revenue is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and we have no remaining performance obligations under the arrangement. If royalties are received when we have remaining performance obligations, we expect to attribute the royalty payments to the services being provided under the arrangement and therefore recognize such royalty payments as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above.

*Deferred Revenue.* Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Significant judgments are required in the application of revenue recognition guidance. For example, in connection with our existing and former collaboration agreements, we have historically recorded on our balance sheet short- and long-term deferred revenue based on our best estimate of when such revenue would be recognized. Short-term deferred revenue would consist of amounts that are expected to be recognized as revenue, or applied against future co-development costs, within the next fiscal year. Amounts that we expect will not be recognized in the next fiscal

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year would be classified as long-term deferred revenue. However, this estimate would be based on our operating plan as of the balance sheet date and on our estimated performance periods under the collaboration in which we have recorded deferred revenues. If our operating plan or our estimated performance period would change, we could recognize a different amount of deferred revenue over the reporting period.

With respect to each of the foregoing areas of revenue recognition, we exercise significant judgment in determining whether an arrangement contains multiple elements, and, if so, how much revenue is allocable to each element. In addition, we exercise our judgment in determining when our significant obligations have been met under such agreements and the specific time periods over which we recognized revenue, such as non-refundable, up-front license fees. To the extent that actual facts and circumstances differ from our initial judgments, our revenue recognition with respect to such transactions would change accordingly and any such change could affect our reported financial results.

### ***Stock-based Compensation***

We have adopted Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), *Share-Based Payment*, which generally requires that stock-based compensation transactions be accounted for using a fair-value-based method and is now referred to as FASB Codification Topic 718, *Compensation - Stock Compensation*.

We have recorded employee and director stock-based compensation expense of \$3,269,000, \$1,642,000 and \$1,979,000 for the years ended December 31, 2012, 2011 and 2010, respectively. We estimate that we will record approximately \$2,700,000, in stock-based compensation expense in 2013. We have granted and expect that we may grant additional options in 2013 that could increase the amount of stock-based compensation ultimately recognized. The amount of the incremental employee stock-based compensation expense attributable to 2013 employee stock options to be granted will depend primarily on the number of stock options granted, the fair market value of our common stock at the respective grant dates, and the specific terms of the stock options.

We measure compensation cost for share-based compensation at fair value, including estimated forfeitures, and recognize the expense as compensation expense over the period that the recipient is required to provide service in exchange for the award, which generally is the vesting period. We use the Black-Scholes option pricing model to measure the fair value of stock options. This model requires significant estimates related to the award's expected life and future stock price volatility of the underlying equity security. In determining the amount of expense to be recorded, we also are required to estimate forfeiture rates for awards, based on the probability that employees will complete the required service period. We estimate the forfeiture rate based on historical experience. If actual forfeitures differ significantly from our estimates, additional adjustments to compensation expense may be required in future periods. Ultimately, the actual expense recognized over the vesting period will only be for those shares that vest.

### ***Fair Value Measurements***

We have adopted the provisions of the FASB Codification Topic 820, *Fair Value Measurements and Disclosures*. Topic 820 provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

GAAP 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



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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.

Our cash equivalents, marketable securities and long-term investments have been classified as either Level 1 or Level 2 assets. We do not hold any asset-backed or auction rate securities. Short-term accounts receivable and accounts payable are reflected in the consolidated financial statements at net realizable value, which approximates fair value due to the short-term nature of these instruments.

In 2010, we completed a registered direct offering in which we issued warrants to purchase shares of our common stock, and the warrants were deemed to be a liability. We estimate the fair value of the warrants using a Black-Scholes option pricing model under various probability-weighted outcomes which take into consideration the protective, but limited, cash-settlement feature of the warrants. In using this model, the fair value is determined by applying Level 3 inputs, which have included assumptions around the estimated future stock price of our common stock and varying probabilities that certain events will occur. Significant increases or decreases in any of these assumptions would materially impact the fair value of the warrants and our financial statements. The warrants will be revalued each reporting period with updated assumptions, and the resulting change in fair value of the warrant liability will be recognized in our financial statements.

While we believe our valuation methodologies are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

***Long-lived Assets***

Long-lived assets consist primarily of property and equipment, debt issuance costs and goodwill. Property and equipment is stated at cost and depreciated over the estimated useful lives of the related assets using the straight-line method. Determining the economic lives of property and equipment requires us to make significant judgments that can materially impact our operating results. If it were determined that the carrying value of our other long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, we would measure an impairment based on application of the FASB Codification Topic 360-10-05, *Impairment or Disposal of Long-Lived Assets*.

Debt issuance costs are stated at cost and amortized over the estimated term of the debt using the straight-line method. Assumptions used in determining the term of the debt requires us to make significant judgments that would impact our operating results; however, we do not believe adjustments to the term of the debt and related amortization period would have a material impact on our financial statements.

We evaluate our goodwill for impairment at least annually or more frequently if an indicator of potential impairment exists. In performing our evaluations of impairment, we determine fair value using widely accepted valuation techniques, including discounted cash flows. These calculations contain uncertainties as they require us to make assumptions related to future cash flows, projected useful lives of assets and the appropriate discount rate to reflect the risk inherent in future cash flows. We must also make assumptions regarding industry

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economic factors and the profitability of future business strategies. If actual results are not consistent with our estimates and assumptions used in estimating future cash flows and asset fair values, we may be exposed to a material impairment charge. As a single reporting unit, we completed our annual goodwill impairment tests in December 2012, 2011 and 2010, and determined that as of those dates our fair value exceeded the carrying value of our net assets. Accordingly, no goodwill impairment was recognized in 2012, 2011 and 2010.

Our discussion of our critical accounting policies is not intended to be a comprehensive discussion of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result.

**Results of Operations (all amounts rounded to the nearest thousand)****Years Ended December 31, 2012 and 2011***Revenues*

Total revenues are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2012	2011	
<b>Revenues:</b>			
<b>Research and development</b>			
Genentech	\$ 363,000	\$ 388,000	(6%)
LLS	1,000,000		100%
Other	79,000	75,000	5%
Subtotal	1,442,000	463,000	211%
<b>License fees</b>			
Genentech	14,000,000	14,000,000	%
Other		300,000	(100%)
Subtotal	14,000,000	14,300,000	(2%)
<b>Royalty revenues from Genentech</b>	1,530,000		100%
Total Revenues	\$ 16,972,000	\$ 14,763,000	15%

Total revenues increased by \$2,209,000, or 15%, for the year ended December 31, 2012 as compared to the prior year, primarily related to royalty revenues of \$1,530,000 from sales of Erivedge during 2012. Erivedge was approved by the FDA for commercial sale in January 2012. In addition, we recognized revenues totaling \$1,000,000 under our agreement with LLS related to the achievement of clinical development objectives during 2012. We are eligible for additional milestone payments totaling \$3,000,000 over the term of our agreement with LLS, if our CUDC-907 program continues to successfully meet clinical development objectives.

Our license fee revenues of \$14,000,000 for the year ended December 31, 2012 are related to payments we received from Genentech upon FDA approval of Erivedge and Roche's filing for marketing registration in Australia. During the year ended December 31, 2011, we recognized \$14,000,000 in license revenue upon FDA and EMA acceptances of Genentech's NDA and MAA filings for Erivedge. All potential future contingent payments under our agreements with Genentech and Debiopharm are tied to clinical and regulatory milestones, which are unpredictable in terms of both timing and whether such milestone will be achieved at all. We are entitled to receive additional payments if Erivedge receives EMA and/or Australian marketing approvals. If Debiopharm progresses Debio 0932 into phase II clinical testing, we will be entitled to payments upon treatment of the fifth patient in up to three such trials.



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Research and development revenues, excluding those earned under our LLS agreement, are limited to expenses that we incur under our collaborations, primarily Genentech, for which our collaborators are obligated to reimburse us.

*Cost of Royalty Revenues.* Cost of royalty revenues of \$176,000 for the year ended December 31, 2012 includes a \$100,000 one-time cash payment paid to a university licensor upon the first commercial sale of Erivedge and \$76,000 paid to two university licensors, which represents 5% of the royalties that we earned with respect to Erivedge. We did not have cost of royalty revenues for the year ended December 31, 2011.

*Operating Expenses*

Research and development expenses are summarized as follows:

Research and Development Program	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2012	2011	
Erivedge	\$ 151,000	\$ 192,000	(21%)
CUDC-427	11,000		100%
CUDC-907	4,046,000	3,201,000	26%
CUDC-101	4,497,000	4,289,000	5%
Debio 0932	57,000	45,000	27%
Other preclinical network-targeted cancer programs	3,541,000	4,604,000	(23%)
Sublicense fees under Genentech collaboration	2,114,000	700,000	202%
Other sublicense fees		15,000	(100%)
Net (gain)/loss on disposition of assets		(77,000)	(100%)
Stock-based compensation	1,075,000	724,000	48%
<b>Total research and development expenses</b>	<b>\$ 15,492,000</b>	<b>\$ 13,693,000</b>	<b>13%</b>

Our research and development expenses increased by \$1,799,000, or 13%, for the year ended December 31, 2012, as compared to the prior year. During the years ended December 31, 2012 and 2011, we incurred sublicense fees of \$2,114,000 and \$700,000, respectively, to various university licensors as a result of the receipt of contingent payments from Genentech for the achievement of regulatory objectives related to Erivedge. The \$1,414,000 increase for the year ended December 31, 2012 was primarily attributable to a one-time issuance of an aggregate of 200,000 shares of our common stock to two university licensors in connection with the FDA-approval of Erivedge with a fair value of \$964,000, as well as an increase in fees owed to university licensors in connection with our obtaining payments from Roche under our collaboration agreement, including a \$450,000 expense specific to development objectives achieved pursuant to Roche's NDA filing in Australia.

Spending on our CUDC-907 program increased \$845,000 for the year ended December 31, 2012 over the prior year primarily related to costs for additional IND-enabling toxicology studies that were completed during 2012, formulation development and clinical trial costs.

Spending related to our CUDC-101 programs increased \$208,000 over the prior year as a result of an increase in employee-related expenses as more resources were allocated to the various CUDC-101 development programs, including the ongoing phase I clinical trial in head and neck cancer patients and the phase I clinical trial with an oral formulation of CUDC-101 that was halted in November 2012. These increases were offset by decreased spending on our CUDC-101 phase Ib trial, as the last patient on trial was treated in October 2011. Further offsetting these increases, spending on our other preclinical network-targeted cancer programs decreased \$1,063,000 when compared to the prior year as our internal resources were primarily allocated to CUDC-101 and CUDC-907.

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Stock-based compensation also increased \$351,000 during the year ended December 31, 2012 from the prior year, primarily related to an increase in the number of and the expense recognized on unvested non-employee stock options that are marked-to-market at each quarterly reporting period. Fluctuations in our stock price over the period will result in comparable fluctuations in the related expense.

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-427, CUDC-907 and CUDC-101. In addition, we will be obligated to pay sublicense fees for (i) any milestone payments we may receive upon achievement of specified regulatory objectives and (ii) royalty payments on net sales of Erivedge in the U.S. We will also be obligated to pay Genentech milestone payments upon the first commercial sale of CUDC-427 in certain territories and royalties on net sales of CUDC-427, if any, and we could be obligated to pay LLS up to a maximum of \$10,000,000 if CUDC-907 is partnered or commercialized on or after completion of a phase IIa trial.

In-process research and development expenses of \$9,500,000 incurred in the year ended December 31, 2012 represent the one-time up-front license payment and technology transfer costs payable to Genentech upon exclusively licensing CUDC-427 in November 2012.

General and administrative expenses are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2012	2011	
Personnel	\$ 2,538,000	\$ 2,472,000	3%
Occupancy and depreciation	515,000	480,000	7%
Legal services	2,521,000	2,137,000	18%
Consulting and professional services	1,233,000	1,110,000	11%
Insurance costs	268,000	248,000	8%
Other general and administrative expenses	799,000	777,000	3%
Stock-based compensation	2,549,000	1,048,000	143%
 Total general and administrative expenses	 \$ 10,423,000	 \$ 8,272,000	 26%

General and administrative expenses increased by \$2,151,000, or 26%, for the year ended December 31, 2012, as compared to the prior year. This increase was primarily due to an increase in stock-based compensation of \$1,501,000 as a result of an increase in the number of and grant-date fair value of options granted to our directors and officers during 2012 as compared to 2011. In addition, legal fees increased \$384,000 from the prior year due to increased costs associated with various corporate matters as well as patent-related costs, including foreign patent filing costs. Consulting and professional service costs increased \$123,000 over the prior year primarily related to business development efforts. Finally, personnel costs increased \$66,000 due to an increase in executive officers' compensation when compared to the prior year.

*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 have an initial exercise price of \$3.55 per share and have a five year term, and the fair value of the warrants is recorded as a long-term liability. The fair value of the warrants has been estimated using a Black-Scholes option pricing model under various probability-weighted outcomes which took into consideration the protective, but limited, cash-settlement feature for the benefit of the warrant holder that expired on January 27, 2012. The warrants are revalued each reporting period, with updated assumptions and the resulting gains and losses recorded as the change in fair value of warrant liability in the statement of operations. Expected volatilities used in the models were based on our historical volatility commensurate with the term of the warrants.

We estimated that the fair value of the warrants at December 31, 2012 was \$1,488,000 using this model with the following assumptions: expected volatility of 58%, risk free interest rate of 0.3%, expected life of 2.1 years

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and no dividends. We estimated that the fair value of the warrants at December 31, 2011 was \$4,361,000 using this same model with the following assumptions assigned to the varying outcomes: expected volatility of 78%, a risk free interest rate of 0.4%, expected life of three years and no dividends.

We recorded other income of \$2,257,000 and a charge of \$2,756,000 for the years ended December 31, 2012 and 2011, respectively, due to the change in the fair value of the warrant liability which was primarily related to the change in our stock price during the respective periods. During the years ended December 31, 2012 and 2011, warrants to purchase 237,301 and 1,504 shares of our common stock were exercised, respectively.

*Other Expense (Income)*

For the year ended December 31, 2012, interest expense was \$204,000 related to accrued interest on the BioPharma II debt transaction. We did not have debt during the year ended December 31, 2011.

For the year ended December 31, 2012, interest income was \$150,000 as compared to \$100,000 for the year ended December 31, 2011, an increase of \$50,000, or 50%, due to higher investment balances throughout 2012 as compared to 2011.

*Net Loss Applicable to Common Stockholders*

As a result of the foregoing, we incurred a net loss applicable to common stockholders of \$16,417,000 for the year ended December 31, 2012, as compared to \$9,859,000 for the year ended December 31, 2011.

*Years Ended December 31, 2011 and 2010**Revenues*

Total revenues are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2011	2010	
Revenues:			
<b>Research and development</b>			
Genentech	\$ 388,000	\$ 275,000	41%
Other	75,000	69,000	9%
<b>Subtotal</b>	<b>463,000</b>	<b>344,000</b>	<b>35%</b>
<b>License fees</b>			
Genentech	14,000,000		100%
Debiopharm		11,333,000	(100%)
Micromet		4,000,000	(100%)
Other	300,000	323,000	(7%)
<b>Subtotal</b>	<b>14,300,000</b>	<b>15,656,000</b>	<b>(9%)</b>
<b>Total Revenues</b>	<b>\$ 14,763,000</b>	<b>\$ 16,000,000</b>	<b>(8%)</b>

Total revenues decreased by \$1,237,000, or 8%, for the year ended December 31, 2011 as compared to the prior year, primarily related to a decrease in license fee revenues of \$1,356,000. During the year ended December 31, 2011, we recognized \$14,000,000 in license revenues relating to milestone payments we received upon FDA and EMA acceptances of Genentech's NDA and MAA filings, respectively, related to Erivedge. During the year ended December 31, 2010, we recorded license fee revenues of \$15,656,000, primarily comprised of an \$11,000,000 payment from Debiopharm upon the achievement of development milestones under our license agreement with Debiopharm as well as settlement proceeds of \$4,000,000 that we received from



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Micromet pursuant to a settlement, mutual release and termination agreement that we entered into with Micromet in February 2010. Because the settlement with Micromet discharged and terminated all future payment obligations that would have arisen under the June 2001 agreement, we do not expect to receive any additional revenues from Micromet.

Research and development revenues increased by \$119,000, or 35%, for the year ended December 31, 2011 as compared to the prior year. The increase was largely due to an increase in expenses that we incurred under our collaborations, primarily our collaboration with Genentech, for which such collaborators were obligated to reimburse us.

*Operating Expenses*

Research and development expenses are summarized as follows:

Research and Development Program	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2011	2010	
Erivedge	\$ 192,000	\$ 192,000	%
CUDC-101	4,289,000	3,327,000	29%
CUDC-907	3,201,000		100%
Debio 0932	45,000	43,000	5%
Other preclinical network-targeted cancer programs	4,604,000	7,237,000	(36%)
Sublicense fees under Genentech collaboration	715,000	9,000	7,844%
Net (gain)/loss on disposition of assets	(77,000)	(98,000)	(21%)
Stock-based compensation	724,000	663,000	9%
<b>Total research and development expenses</b>	<b>\$ 13,693,000</b>	<b>\$ 11,373,000</b>	<b>20%</b>

Our research and development expenses increased by \$2,320,000, or 20%, for the year ended December 31, 2011, as compared to the prior year. The increase in research and development expenses was the result of a \$962,000 increase in spending related to our CUDC-101 program, which primarily related to outside services and clinical costs, including our phase I expansion trial for which we completed patient dosing in October 2011, costs related to our phase I trial in locally advanced HPV- head and neck cancers and manufacturing and toxicology costs related to an oral formulation of CUDC-101. In addition, spending related to our CUDC-907 program increased \$3,201,000 over the prior year period as a result of shifting resources from our other network-targeted cancer programs. Our 2011 spending on our other network-targeted cancer programs decreased by \$2,633,000 when compared to 2010. CUDC-907 was selected as a development candidate in January 2011. During the year ended December 31, 2011, we also incurred expenses of \$700,000 in sublicense payments that we made as a result of receiving \$14,000,000 from Genentech during 2011 for the achievement of regulatory objectives related to Erivedge. No such expenses were incurred under the Genentech collaboration during the year ended December 31, 2010.

General and administrative expenses are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2011	2010	
Personnel	\$ 2,472,000	\$ 2,648,000	(7%)
Occupancy and depreciation	480,000	401,000	20%
Legal services	2,137,000	3,552,000	(40%)
Consulting and professional services	1,110,000	1,348,000	(18%)
Insurance costs	248,000	256,000	(3%)
Other general and administrative expenses	777,000	756,000	3%
Stock-based compensation	1,048,000	1,304,000	(20%)
<b>Total general and administrative expenses</b>	<b>\$ 8,272,000</b>	<b>\$ 10,265,000</b>	<b>(19%)</b>





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General and administrative expenses decreased by \$1,993,000, or 19%, for the year ended December 31, 2011, as compared to the prior year. This decrease was related to a reduction in spending in several areas, primarily for legal services. During the year ended December 31, 2010, we incurred approximately \$1,526,000 in expenses related to an arbitration proceeding that we filed against our former collaborator that we did not incur during the year ended December 31, 2011. In addition, legal costs associated with various matters decreased \$212,000 from the prior year period. Offsetting these decreases in legal spending, our patent-related costs increased \$323,000 in the year ended December 31, 2011 as compared to the prior year period primarily related to fees for foreign patent, opposition and interference filings. Consulting and professional services decreased \$238,000 for the year ended December 31, 2011, as compared to the prior year. During the year ended December 31, 2010, we incurred consulting and professional services specifically related to business development efforts used to facilitate the licensing agreement with Debiopharm.

Personnel costs decreased \$176,000 during the year ended December 31, 2011 compared to the year ended year ended December 31, 2010, primarily resulting from discretionary bonuses paid to our executive officers in 2010. Stock-based compensation also decreased \$256,000 during the year ended December 31, 2011 from the prior year, primarily related to vesting of certain performance-based stock options in the first quarter of 2010 that did not occur during 2011. Partially offsetting these decreases, our allocated occupancy costs increased \$79,000 for the year ended December 31, 2011 compared to the year ended year ended December 31, 2010.

*Change in fair value of warrant liability.* As a result of revaluing the warrants issued in January 2010, we recorded a charge of \$2,756,000 and a gain of \$576,000 for the years ended December 31, 2011 and 2010, respectively, as a result of the change in the fair value of the warrant liability from December 31, 2010 and from issuance, respectively.

### *Other Income*

For the year ended December 31, 2011, interest and other income was \$100,000 as compared to \$627,000 for the year ended December 31, 2010, a decrease of \$527,000, or 84%. The decrease relates to federal tax grants totaling \$489,000 that we received in the fourth quarter of 2010 under the Patient Protection and Affordable Care Act of 2010 that we did not receive in 2011. In addition, interest income decreased \$38,000 from the prior year period due to lower investment balances throughout 2011 as compared to 2010.

### *Net Loss Applicable to Common Stockholders*

As a result of the foregoing, we incurred a net loss applicable to common stockholders of \$9,859,000 for the year ended December 31, 2011, as compared to \$4,435,000 for the year ended December 31, 2010.

## **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.

In 2012, we received a milestone payment of \$10,000,000 based upon the FDA approval of Erivedge, and we received a \$4,000,000 milestone payment in connection with Roche's filing of an application for marketing registration in Australia. We also received royalty revenues of \$1,530,000 in connection with Genentech's net sales of Erivedge during the year ended December 31, 2012. During the fourth quarter of 2011, Roche submitted an MAA for Erivedge to the EMA for which we earned a \$6,000,000 milestone payment. Upon receipt of these payments, we made payments totaling \$1,626,000 related to obligations to certain university licensors.

In December 2012, we entered into a \$30,000,000 debt transaction at an annual interest rate of 12.25% secured with certain future Erivedge royalty and royalty-related payment streams with BioPharma-II. Under the

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terms of the loan, quarterly royalty payments 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 \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$3,000,000 per quarter in 2015, will be applied first, to pay interest and second, principal on the loan. We 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 and 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 and the termination of Curis Royalty's right to receive royalties under the collaboration agreement with Genentech.

At December 31, 2012, our principal sources of liquidity consisted of cash, cash equivalents, and investments of \$58,701,000, excluding our restricted investments of \$194,000. 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, 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 assuming that CUDC-427, CUDC-907 and CUDC-101 advance into further stages of clinical testing.

Operating activities used cash of \$15,193,000 for the year ended December 31, 2012, which was primarily the result of our net loss for the period of \$16,417,000, offset by non-cash charges totaling \$2,028,000 consisting of stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense, the issuance of common stock to licensees and depreciation. We received \$15,530,000 in milestone and royalty payments from Genentech as well as \$1,000,000 in milestone payments from LLS during the period. Offsetting these cash receipts, we incurred operating and other expenses of \$33,389,000 for the year ended December 31, 2012, of which \$9,500,000 relates to one-time charges for the license of CUDC-427 from Genentech. Changes in certain operating assets and liabilities had offsetting impacts on operating cash during the year ended December 31, 2012. Finally, an increase of \$866,000 in our accounts receivable, primarily related to quarterly royalties earned on the sale of Erivedge, decreased operating cash.

Cash used in operating activities of \$4,563,000 during the year ended December 31, 2011 was primarily the result of our net loss for the period of \$9,859,000, partially offset by non-cash charges totaling \$4,805,000 consisting of stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense, depreciation and a gain on the sale of assets. We received \$14,000,000 in payments from Genentech during the year ended December 31, 2011. Offsetting these cash receipts, we incurred operating and other expenses of \$24,621,000 for the year ended December 31, 2011. In addition, changes in certain operating assets and liabilities increased operating cash during the year ended December 31, 2011, primarily related to an increase in our accounts payable and accrued liabilities of \$416,000.

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

Investing activities used cash of \$23,003,000 for year ended December 31, 2012 and provided cash of \$9,776,000 for the year ended December 31, 2011, resulting primarily from net investment activity for the

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respective periods. The increase in investments during the year ended December 31, 2012 was the result of an increase in cash receipts from the prior year, while the decrease during the year ended December 31, 2011, was a result of the need for cash in order to fund our operations. In addition, during the years ended December 31, 2012 and 2011, we reduced our restricted investments, resulting in an increase in our available cash for the periods of \$42,000 and \$261,000, respectively. During the year ended December 31, 2011, the restriction on our short-term investment ended and we reduced our long-term restricted investment resulting in an increase in our available cash for the period. These increases in cash were offset by purchases of research equipment totaling \$105,000 and \$260,000 during the years ended December 31, 2012 and 2011, respectively.

Financing activities provided cash of \$35,825,000 and \$2,081,000 for the years ended December 31, 2012 and 2011, respectively. The increase during the year ended December 31, 2012, was primarily related to the debt financing transaction secured by Erivedge royalties, that provided proceeds of \$30,000,000, marginally offset by related issuance costs of \$160,000. Under the terms of the loan, interest will accrue at 12.25% per annum and quarterly payments, subject to certain caps, will be applied to pay interest and principal on the loan after deducting royalty obligations for university licensors and certain other specified payments. The final maturity date of the loan will be the earlier of the date when the principal is paid in full and the termination of Curis Royalty's right to receive royalties under the collaboration agreement with Genentech. The exercise of stock options and warrants and purchases of common stock under our employee stock purchase plan provided cash of \$5,106,000 and \$1,792,000 for the years ended December 31, 2012 and 2011, respectively. We issued 2,489,249 shares of our common stock related to these exercises and purchases during the year ended December 31, 2012 compared to 1,257,374 shares for the year ended December 31, 2011. We also received \$879,000 and \$289,000 in net proceeds from sales of common stock under our At Market Issuance Sales Agreement, or ATM Agreement, with McNicoll, Lewis & Vlak, LLC, or MLV, for the years ended December 31, 2012 and 2011, respectively.

*Funding Requirements*

We have incurred significant losses since our inception. As of December 31, 2012, we had an accumulated deficit of approximately \$748,505,000. 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-427, CUDC-907 and CUDC-101, and to fund our general and administrative costs and expenses.

We have historically derived a substantial portion of our operating cash flow from the research funding portion of collaboration agreements with third parties. However, we have no current research funding revenue 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 and the ability of Erivedge to be approved for commercial sale in other countries, which would result in us becoming eligible to receive additional milestone payments as well as royalties on any future sales (subject to our obligation to transfer certain royalties to BioPharma-II pursuant to the terms of our credit agreement). 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 collaborations with Genentech, Debiopharm and LLS; 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 our obligation to transfer certain royalties to BioPharma-II pursuant to the terms of our credit agreement.

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We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of us receiving payments under such collaborations is highly uncertain. For example, the amount of future royalty payments that we will receive as a result of Genentech's U.S. net sales of Erivedge, as well as potential future royalty payments that we may receive on net sales of Erivedge in territories outside of the U.S., to the extent that Genentech successfully obtains marketing approval in such territories, is highly uncertain. In addition, we will only receive royalties over certain quarterly caps through 2015, if any, as the Erivedge royalties will service the outstanding debt to BioPharma-II until the loan is paid in full.

We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at December 31, 2012, should enable us to maintain current and planned operations into mid-2015. 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;

the timing, receipt and amount of payments, if any, from current and potential future collaborators;

the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates, including the level of any royalty payments from sales of Erivedge, which could increase the outstanding debt due to BioPharma-II if the royalty payments are insufficient to cover the accrued interest when payments are due;

unplanned costs to prepare, file, prosecute, maintain 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, are highly volatile. Due to this and various other factors, including potentially adverse general market conditions and the early-stage status of our internal development pipeline 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

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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.

**Table of Contents****Contractual Obligations**

In addition to our credit agreement with BioPharma-II, we had contractual obligations and other commitments, including an operating lease related to our facility, research services agreements, consulting agreements, and license agreements, as follows as of December 31, 2012:

	Total	Payment Due By Period (amounts in 000 s)			
		Less than One Year	One to Three Years	Three to Five Years	More than Five Years
Debt obligations under credit agreement(1)	\$ 41,933	\$ 3,457	\$ 18,498	\$ 19,978	\$
Operating lease obligations(2)	3,315	602	1,278	1,376	59
Outside service obligations(3)	508	275	233		
Licensing obligations(4)	115	115			
<b>Total future obligations</b>	<b>\$ 45,871</b>	<b>\$ 4,449</b>	<b>\$ 20,009</b>	<b>\$ 21,354</b>	<b>\$ 59</b>

- (1) On December 11, 2012, we entered into a debt financing transaction secured by Erivedge royalties that provided gross proceeds of \$30,000,000. Under the terms of the loan, interest will accrue at 12.25% per annum and quarterly payments, subject to certain caps, will be applied to pay interest and principal on the loan after deducting royalty obligations for university licensors. The final maturity date of the loan will be the earlier of the date when the principal is paid in full and the termination of Curis Royalty's right to receive royalties under the collaboration agreement with Genentech. As of December 31, 2012, the outstanding balance, including interest, of the debt was \$30,204,000. The above amounts reflect management's estimates of repayments, including accrued interest payments, based on assumptions of future Erivedge royalties as of December 31, 2012. If future royalties are lower or higher than these assumptions, the repayment period will increase or decrease, respectively, and related debt payments will fluctuate accordingly.
- (2) Effective September 16, 2010, we entered into a new lease agreement with the Trustees of Lexington Office Realty Trust pursuant to which we lease 24,529 square feet of property for office, research and laboratory space located at 4 Maguire Road in Lexington, Massachusetts. The term of the lease agreement commenced on December 1, 2010, and expires in February 2018. The total remaining cash obligation for the base rent over the initial term of the lease agreement is approximately \$3,315,000. In addition to the base rent, we are responsible for our share of operating expenses and real estate taxes, in accordance with the terms of the lease agreement. Amounts include contractual rent payments and exclude any impact of an early termination payment as defined in the agreement.
- (3) Outside service obligations consist of agreements we have with outside labs, consultants and various other service organizations. Obligations to clinical research organizations, medical centers and hospitals conducting our clinical trials are included in our financial statements for costs incurred as of December 31, 2012. Our obligations under these types of arrangements are limited to actual costs incurred for services performed and do not include any contingent or milestone payments.
- (4) Licensing obligations include only obligations that are known to us as of December 31, 2012. In the future, we may owe royalties and other contingent payments to our licensors based on the achievement of developmental milestones, product sales and specified other objectives. For example, contingent payments to sublicensees related to future development milestones would total \$3,450,000, or 5%, if all of the \$69,000,000 in remaining milestones under our June 2003 Genentech collaboration are achieved. We are required to make payments to university licensors on any royalties that we receive upon the sale of Erivedge and to make milestone payments to Genentech under our license agreement for CUDC-427. For example, the first milestone for CUDC-427 is payable upon the first commercial sale of a product containing CUDC-427. We are also obligated to make payments of up to \$10,000,000 to LLS under our agreement for CUDC-907. This obligation is limited to 2.5 times the amount that we receive from LLS, and, as of December 31, 2012, the maximum obligation, assuming that CUDC-907 successfully progresses through

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future clinical trials, would be \$2,500,000. These future obligations are not reflected in the table above as these payments are contingent upon achievement of developmental and commercial milestones, the likelihood of which cannot be reasonably estimated at this time.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of December 31, 2012.

### **Inflation**

We believe that inflation has not had a significant impact on our revenue and results of operations since inception.

### **New Accounting Pronouncements**

In July 2012, the FASB issued amended accounting guidance for testing indefinite-lived intangible assets for impairment. The amendments permit a company to first assess the qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. The more-likely-than-not threshold is defined as having a likelihood of more than 50 percent. If, after assessing the totality of events or circumstances, a company concludes it is more likely than not that the fair value of the indefinite-lived intangible asset exceeds its carrying value, then the company is not required to take further action. A company also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. A company will be able to resume performing the qualitative assessment in any subsequent period. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. We did not elect to early adopt and we do not expect the adoption to have any impact on our consolidated financial statements.

In February 2013, the FASB issued amended accounting guidance for reporting accumulated other comprehensive income. The amendments require a company to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, a company is required to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income, a company is required to cross-reference to other disclosures required under U.S. GAAP that provide additional detail about those amounts. The amendments are effective prospectively for reporting periods beginning after December 15, 2012. Other than a change in presentation, the adoption of this guidance is not expected to have an impact on our consolidated financial statements.



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**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our current cash balances in excess of operating requirements are invested in cash equivalents, short-term marketable securities, which consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations with an average maturity of less than one year, 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 economic downturn and volatile business environment and continued unpredictable and unstable market conditions. Our marketable securities and long-term investments are subject to interest rate risk and will fall in value if market interest rates increase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, marketable securities or long-term investments since December 31, 2012, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities and long-term investments owned by us. To help manage this risk, we limit our investments to investment grade securities and deposits are with investment grade financial institutions. We believe that the realization of losses due to changes in credit spreads is unlikely as we currently have the ability to hold our investments for a sufficient period of time to recover the fair value of the investment and there is sufficient evidence to indicate that the fair value of the investment is recoverable. We do not use derivative financial instruments in our investment portfolio. We do not believe that a 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.

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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and our directors; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment our management used the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO.

Based on our assessment, management concluded that, as of December 31, 2012, our internal control over financial reporting is effective based on the criteria established in *Internal Control Integrated Framework* issued by COSO.

The effectiveness of internal control over financial reporting as of December 31, 2012 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, who has issued an attestation report on the our internal control over financial reporting which appears herein.

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of Curis, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Curis, Inc. and its subsidiaries at December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PRICEWATERHOUSECOOPERS LLP  
Boston, Massachusetts  
March 13, 2013

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Consolidated Balance Sheets**

	December 31,	
	2012	2011
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 12,747,709	\$ 15,119,730
Investments	42,791,689	22,597,845
Short-term investment restricted	13,877	
Accounts receivable	908,064	42,067
Prepaid expenses and other current assets	390,564	743,799
Total current assets	56,851,903	38,503,441
Property and equipment, net	434,168	455,730
Long-term investments	3,162,025	
Long-term investment restricted	180,405	235,914
Goodwill	8,982,000	8,982,000
Other assets	157,848	2,980
Total assets	\$ 69,768,349	\$ 48,180,065
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 2,504,270	\$ 2,364,437
Accrued liabilities	1,474,556	1,422,107
Total current liabilities	3,978,826	3,786,544
Debt, net	29,838,925	
Warrants	1,488,179	4,361,168
Other long-term liabilities	194,921	156,396
Total liabilities	35,500,851	8,304,108
Commitments (Note 9)		
Stockholders Equity:		
Common stock, \$0.01 par value 125,000,000 shares authorized; 81,065,488 shares issued and 80,017,781 shares outstanding at December 31, 2012; and 78,165,360 shares issued and 77,117,653 shares outstanding at December 31, 2011	810,655	781,654
Additional paid-in capital	782,837,507	772,039,254
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Accumulated deficit	(748,504,549)	(732,087,642)
Accumulated other comprehensive income	15,159	33,965
Total stockholders equity	34,267,498	39,875,957
Total liabilities and stockholders equity	\$ 69,768,349	\$ 48,180,065

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



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Consolidated Statements of Operations and Comprehensive Loss**

	Years Ended December 31,		
	2012	2011	2010
<b>Revenues:</b>			
License fees	\$ 14,000,000	\$ 14,300,000	\$ 15,655,833
Royalties	1,529,644		
Research and development	1,442,347	462,580	343,732
<b>Total revenues</b>	<b>16,971,991</b>	<b>14,762,580</b>	<b>15,999,565</b>
<b>Costs and Expenses:</b>			
Cost of royalty revenues	176,482		
Research and development	15,492,302	13,692,659	11,372,850
In-process research and development	9,500,000		
General and administrative	10,423,014	8,272,424	10,264,459
<b>Total costs and expenses</b>	<b>35,591,798</b>	<b>21,965,083</b>	<b>21,637,309</b>
Loss from operations	(18,619,807)	(7,202,503)	(5,637,744)
<b>Other Income (Expense):</b>			
Interest income	149,937	100,034	137,662
Interest expense	(204,167)		
Change in fair value of warrant liability	2,257,130	(2,756,426)	575,813
Other income			488,959
<b>Total other income (expense)</b>	<b>2,202,900</b>	<b>(2,656,392)</b>	<b>1,202,434</b>
<b>Net loss</b>	<b>\$ (16,416,907)</b>	<b>\$ (9,858,895)</b>	<b>\$ (4,435,310)</b>
Net Loss per Common Share (Basic and Diluted)	\$ (0.21)	\$ (0.13)	\$ (0.06)
<b>Weighted Average Common Shares (Basic and Diluted)</b>	<b>79,059,153</b>	<b>76,351,856</b>	<b>74,959,158</b>
<b>Net Loss</b>	<b>\$ (16,416,907)</b>	<b>\$ (9,858,895)</b>	<b>\$ (4,435,310)</b>
<b>Other comprehensive loss, net of tax:</b>			
Unrealized (loss) gain on marketable securities	(18,806)	(11,397)	44,725
<b>Comprehensive loss</b>	<b>\$ (16,435,713)</b>	<b>\$ (9,870,292)</b>	<b>\$ (4,390,585)</b>

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

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Consolidated Statements of Stockholders' Equity**

	Common Stock		Additional Paid-in Capital	Treasury Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders Equity
	Shares	Amount						
Balance, December 31, 2009	68,360,067	\$ 683,601	\$ 751,068,635	\$ (891,274)	\$ (15,904)	\$ (717,793,437)	\$ 637	\$ 33,052,258
Issuance of common stock in conjunction with the registered direct offering, net of issuance costs of \$1,310,000 and net of fair value of warrants of \$2,180,555	6,449,288	64,493	12,697,269					12,761,762
Issuances of common stock upon the exercise of warrants	1,742,671	17,427	1,760,097					1,777,524
Other issuances of common stock	251,842	2,518	347,058					349,576
Recognition of employee stock-based compensation			1,979,090					1,979,090
Mark-to-market on stock options to non-employees			(26,917)		26,917			
Amortization of deferred compensation					(11,968)			(11,968)
Other comprehensive income							44,725	44,725
Net loss						(4,435,310)		(4,435,310)
Balance, December 31, 2010	76,803,868	768,039	767,825,232	(891,274)	(955)	(722,228,747)	45,362	45,517,657
Issuances of common stock upon the exercise of warrants and stock options, for purchases under the ESPP, and pursuant to sales of shares under	1,361,492	13,615	2,442,866					2,456,481

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the Company's ATM agreement (see Note 10), net of \$128,155 in ATM issuance costs								
Recognition of employee stock-based compensation			1,641,830					1,641,830
Mark-to-market on stock options to non-employees			129,326		955			130,281
Other comprehensive loss						(11,397)		(11,397)
Net loss						(9,858,895)		(9,858,895)
Balance, December 31, 2011	78,165,360	781,654	772,039,254	(891,274)		(732,087,642)	33,965	39,875,957
Issuances of common stock upon the exercise of warrants and stock options, for purchases under the ESPP, and pursuant to sales of shares under the Company's ATM agreement (see Note 10), net of \$27,356 in ATM issuance costs and including fair value of warrants exercised of \$615,859	2,700,128	27,001	6,212,342					6,239,343
Issuance of common stock to licensors	200,000	2,000	962,000					964,000
Recognition of employee stock-based compensation			3,268,689					3,268,689
Mark-to-market on stock options to non-employees			355,222					355,222
Other comprehensive loss						(18,806)		(18,806)
Net loss						(16,416,907)		(16,416,907)
Balance, December 31, 2012	81,065,488	\$ 810,655	\$ 782,837,507	\$ (891,274)		\$ (748,504,549)	\$ 15,159	\$ 34,267,498

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





**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2012	2011	2010
<b>Cash Flows from Operating Activities:</b>			
Net loss	\$ (16,416,907)	\$ (9,858,895)	\$ (4,435,310)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	126,537	107,396	686,495
Stock-based compensation expense	3,623,911	1,772,111	1,967,122
Issuance of common stock to licensees	964,000		
Change in fair value of warrant liability	(2,257,130)	2,756,426	(575,813)
Amortization of debt issuance costs	5,769		
Non-cash interest (income)/expense	(434,763)	246,122	(316,560)
Gain on sale of fixed assets and equipment		(77,068)	(98,107)
Changes in operating assets and liabilities:			
Accounts receivable	(865,997)	50,304	423,387
Prepaid expenses and other assets	40,959	24,111	239,934
Accounts payable and accrued and other liabilities	20,316	416,196	955,586
Deferred revenue			(475,833)
Total adjustments	1,223,602	5,295,598	2,806,211
Net cash used in operating activities	(15,193,305)	(4,563,297)	(1,629,099)
<b>Cash Flows from Investing Activities:</b>			
Purchases of investments	(69,153,956)	(42,136,949)	(65,897,078)
Sales of investments	46,214,044	51,834,854	51,464,558
Net decrease/(increase) in restricted cash/investments	41,632	261,090	(281,002)
Expenditures for property and equipment	(104,975)	(260,405)	(274,840)
Proceeds from sale of fixed assets and equipment		77,068	99,160
Net cash (used in) provided by investing activities	(23,003,255)	9,775,658	(14,889,202)
<b>Cash Flows from Financing Activities:</b>			
Proceeds from issuance of common stock associated with offerings, net of issuance costs (see Note 10)	879,080	288,817	14,942,317
Proceeds from issuance of common stock under the Company's share-based compensation plans and warrant exercises	5,105,699	1,792,003	2,127,100
Payment of debt issuance costs	(160,240)		
Proceeds from issuance of debt	30,000,000		
Net cash provided by financing activities	35,824,539	2,080,820	17,069,417
Net (decrease) increase in cash and cash equivalents	(2,372,021)	7,293,181	551,116
Cash and cash equivalents, beginning of period	15,119,730	7,826,549	7,275,433
Cash and cash equivalents, end of period	\$ 12,747,709	\$ 15,119,730	\$ 7,826,549
Supplemental cash flow data related to non-cash items:			
Receivable for issuances of common stock	\$ 14,366	\$ 375,661	\$

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Unpaid debt issuance costs	\$	261,475	\$	\$
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The accompanying notes are an integral part of these consolidated financial statements.

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**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements**

**(1) OPERATIONS**

Curis, Inc. (the Company or Curis) is an oncology-focused company seeking to develop and commercialize next generation targeted small molecule drug candidates for cancer treatment. Curis is building upon its past experiences in targeting signaling pathways, including the Hedgehog signaling pathway, in its efforts to develop network-targeted cancer therapies. Curis conducts research and development programs both internally and through strategic collaborations and partnerships.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any successful products would be used in the health care industry and would be regulated in the United States, or the U.S., by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory agencies. In January 2012, the FDA approved the Erivedge capsule for treatment of adults with basal cell carcinoma, or BCC, that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. Erivedge is being developed and commercialized by F. Hoffmann-La Roche Ltd, or Roche, and Genentech Inc., or Genentech, a member of the Roche Group, under a collaboration agreement between the Company and Genentech (see Note 3(a)).

The Company is subject to risks common to companies in the biotechnology industry as well as risk factors that are specific to the Company's business, including, but not limited to: the Company's reliance on Genentech and Roche to successfully commercialize Erivedge in the U.S. market and to seek approval for Erivedge in territories outside of the U.S. in the lead indication of advanced BCC; the Company's ability to advance its research and development programs, including those programs developed directly by the Company and those that are being developed by its collaborators and licensees; the potential for the Company to expand its research and development programs, either through internal discovery or through the licensing or acquisition of third-party programs; the Company's ability to obtain adequate financing to fund its operations; the Company's ability to satisfy the terms of its agreements with BioPharma Secured Debt Fund II Sub, S.à r.l., a Luxembourg limited liability company managed by Pharmakon Advisors, or BioPharma-II; its ability to obtain and maintain intellectual property protection for its proprietary technology; development by its competitors of new or better technological innovations; dependence on key personnel and the Company's ability to attract and retain such key personnel; its ability to comply with FDA regulations and approval requirements; and its ability to execute on its overall business strategies.

The Company's future operating results will largely depend on the magnitude of payments from its current and potential future corporate collaborators and the progress of drug candidates currently in its development pipeline. The results of the Company's operations will vary significantly from year to year and quarter to quarter and depend on, a number of factors, including, but not limited to: Genentech's ability to successfully scale-up the commercialization of Erivedge in advanced BCC in the U.S.; Genentech's and/or Roche's receipt of approval to commercialize Erivedge in advanced BCC in Europe and other territories as well as its ability to successfully launch and commercialize Erivedge in these markets; positive results in Genentech's ongoing phase II clinical trial in patients with operable BCC; the timing, outcome and cost of the Company's planned clinical trials for CUDC-427, CUDC-907, CUDC-101 and other potential research and development programs; and the Company's ability to successfully enter into one or more material licenses or collaboration agreements for its proprietary drug candidates.

The Company anticipates that existing cash, cash equivalents, marketable securities, investments and working capital at December 31, 2012 should enable us to maintain current and planned operations for the foreseeable future. The Company's ability to continue funding its planned operations is dependent

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upon, among other things, the success of its collaborations with Genentech, the Leukemia & Lymphoma Society, or LLS, and Debiopharm S.A., or Debiopharm, including its receipt of additional contingent cash payments under these collaborations; and its ability to control expenses and its ability to raise additional funds through equity or debt financings, new collaborations or other sources of financing. The Company may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations is highly uncertain. As a result, the Company may not be able to attain any further revenue under any collaborations or licensing arrangements. 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) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**(a) USE OF ESTIMATES**

The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts and disclosure of revenue, expenses and certain assets and liabilities at the balance sheet date. Such estimates include the performance obligations under the Company's collaboration agreements; the estimated repayment term of the Company's debt and related short- and long-term classification; the collectibility of receivables; the carrying value of property and equipment and intangible assets; the assumptions used in the Company's valuation of stock-based compensation and the value of certain investments and liabilities, including our long-term warrant liability. Actual results may differ from such estimates.

**(b) CONSOLIDATION**

The accompanying consolidated financial statements include the Company and its wholly owned subsidiaries, Curis Royalty LLC, or Curis Royalty (see Note 8), Curis Securities Corporation, Inc. and Curis Pharmaceuticals (Shanghai) Co., Ltd., or Curis Shanghai. The Company has eliminated all intercompany transactions in each of the years ended December 31, 2012, 2011 and 2010.

**(c) REVENUE RECOGNITION**

The Company's business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company's drug candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales. The Company follows the provisions of the Financial Accounting Standards Board, or FASB, Codification Topic 605, *Revenue Recognition*.

**License Fees and Multiple Element Arrangements**

In January 2011, the Company adopted a new U.S. generally accepted accounting principles, or GAAP, accounting standard on a prospective basis which amends existing revenue recognition accounting guidance to provide accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This new guidance eliminates the requirement to establish objective evidence of fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no vendor-specific objective evidence or third-party evidence to determine the fair value of that undelivered item.

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For multiple element arrangements, including license agreements, entered into prior to January 1, 2010, guidance required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under this guidance, if the fair value of all of the undelivered elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined.

Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with GAAP. The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations, typically including research and/or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

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

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. The Company recognizes revenue using the relative performance method provided that the Company can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance. Revenue recognized under the relative performance method would be determined by multiplying the total payments under the contract, excluding royalties and payments contingent upon achievement of substantive milestones, by the ratio of level of effort incurred to date to estimated total level of effort required to complete the Company's performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If the Company cannot reasonably estimate the level of effort required to complete its performance obligations under an arrangement, the performance obligations are provided on a best-efforts basis and the Company can reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period the Company expects to complete its performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

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If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

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

### **Substantive Milestone Payments**

In April 2010, the FASB issued guidance on the milestone method for revenue recognition purposes. Previously, definitive guidance on when the use of the milestone method was appropriate did not exist. This guidance provides a framework of the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate.

Collaboration agreements that contain substantive milestone payments are recognized upon achievement of the milestone only if:

such milestone is commensurate with either of the following:

- a) the vendor's performance to achieve the milestone (for example, the achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement); or
- b) the enhancement of the value of the deliverable as a result of a specific outcome resulting from the vendor's performance to achieve the milestone (or substantive Company effort is involved in achieving the milestone);

such milestone relates solely to past performance; and

the amount of the milestone payment is reasonable relative to all deliverables and payment terms in the arrangement.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and the resulting payment would be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above. In addition, the determination that one such payment was not a substantive milestone could prevent the Company from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable. Milestones that are tied to regulatory approval are not considered probable of being achieved until such approval is received. Milestones tied to counter-party performance are not included in the Company's revenue model until the performance conditions are met.

### **Reimbursement of Costs**

Reimbursement of research and development costs by third party collaborators is recognized as revenue provided the Company has determined that it is acting primarily as a principal in the transaction according to the provisions outlined in the FASB Codification Topic 605-45, *Revenue Recognition, Principal Agent Considerations*, the amounts are determinable and collection of the related receivable is reasonably assured.

**Table of Contents****Royalty Revenue**

Since the first quarter of 2012, the Company has recognized royalty revenues related to Genentech's sales of Erivedge in the U.S. The Company expects to recognize royalty revenue in future quarters from Genentech's sales of Erivedge in the U.S. and in other markets where Genentech and Roche successfully obtain marketing approval, if any (see Notes 3(a) and 8). Royalty revenue is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and the Company has no remaining performance obligations under the arrangement. If royalties are received when the Company has remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and therefore would be recognized as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above.

**Deferred Revenue**

Amounts received prior to satisfying the above revenue recognition criteria would be recorded as short term deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during the year ending December 31, 2013 would be classified as long-term deferred revenue. As of December 31, 2012 and 2011, the Company had no amounts classified as short-term or long-term deferred revenue.

**Summary**

During the years ended December 31, 2012, 2011 and 2010, total gross revenues from major current and former licensees as a percent of total gross revenues of the Company were as follows:

	Year Ended December 31,		
	2012	2011	2010
Genentech	94%	97%	2%
LLS	6%	%	%
Debiopharm	%	%	71%
Micromet settlement proceeds	%	%	25%

**(d) RESEARCH AND DEVELOPMENT**

Research and development expense consists of costs incurred to discover, research and develop drug candidates. These expenses consist primarily of: (1) salaries and related expenses for personnel including stock-based compensation expense; (2) outside service costs, including clinical research organizations and medicinal chemistry; (3) sublicense payments; and (4) the costs of supplies and reagents, consulting, and occupancy and depreciation charges. In addition, the Company incurred in-process research and development expenses of \$9,500,000 during the year ended December 31, 2012, representing the one-time license and technology transfer fee related to the license of CUDC-427 from Genentech (see Note 3(b)). The Company expenses research and development costs as incurred.

The Company is currently recognizing cost of royalties on Erivedge royalties earned under the June 2003 collaboration with Genentech related to obligations to third-party university licensors. The Company is also incurring research and development expenses under this collaboration related to the maintenance of these third-party licenses to certain background technologies. In addition, the Company records research and development expense for obligations to certain third-party university licensors upon earning payments from Genentech related to the achievement of clinical development and regulatory objectives under this collaboration as well as upon royalties earned for Erivedge (see Note 3(a)).



**Table of Contents****(e) CASH EQUIVALENTS, MARKETABLE SECURITIES AND INVESTMENTS**

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

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

The amortized cost, unrealized gains and fair value of marketable securities available-for-sale as of December 31, 2012, with maturity dates ranging between one and twelve months and with a weighted average maturity of 5.2 months are as follows:

	<b>Amortized Cost</b>	<b>Unrealized Gain</b>	<b>Fair Value</b>
Corporate bonds and notes	\$ 42,775,952	\$ 15,737	\$ 42,791,689
Total marketable securities	\$ 42,775,952	\$ 15,737	\$ 42,791,689

As of December 31, 2012, the Company recorded long-term investments of \$3,162,025 on its Consolidated Balance Sheet. This amount is comprised of corporate debt securities with maturities ranging from March 2014 to May 2014 and with amortized cost totaling \$3,161,848, plus unrealized net gains of \$177.

The amortized cost, unrealized gains and fair value of marketable securities available-for-sale as of December 31, 2011, with maturity dates ranging between one and twelve months and with a weighted average maturity of 3.7 months are as follows:

	<b>Amortized Cost</b>	<b>Unrealized Gain</b>	<b>Fair Value</b>
U.S. Government obligations	\$ 3,808,641	\$ 63	\$ 3,808,704
Corporate bonds, notes and stock	1		
	8,787,778	1,363	18,789,141
Total marketable securities	\$ 22,596,419	\$ 1,426	\$ 22,597,845

**(f) FAIR VALUE OF FINANCIAL INSTRUMENTS**

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 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



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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 10, and is therefore classified as Level 3.

In accordance with the fair value hierarchy, the following table shows the fair value as of December 31, 2012 and 2011 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 December 31, 2012 and 2011.

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
<b>As of December 31, 2012:</b>				
Cash equivalents				
Money market funds	\$ 7,597,598	\$	\$	\$ 7,597,598
Corporate commercial paper, bonds and notes	2,263,323			2,263,323
Municipal bonds		1,825,000		1,825,000
Short- and long-term investments				
Corporate commercial paper, bonds and notes	13,366,420	32,587,294		45,953,714
Total assets at fair value	\$ 23,227,341	\$ 34,412,294	\$	\$ 57,639,635
Warrants			1,448,179	1,448,179
Total liabilities at fair value	\$	\$	\$ 1,448,179	\$ 1,448,179
<b>As of December 31, 2011:</b>				
Cash equivalents				
Money market funds	\$ 5,366,747	\$	\$	\$ 5,366,747
Municipal bonds	2,375,000			2,375,000
Short-term investments				
US government obligations		3,808,704		3,808,704
Corporate commercial paper, stock, bonds and notes	7,365,841	11,423,300		18,789,141
Total assets at fair value	\$ 15,107,588	\$ 15,232,004	\$	\$ 30,339,592
Warrants			4,361,168	4,361,168
Total liabilities at fair value	\$	\$	\$ 4,361,168	\$ 4,361,168

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The following table rolls forward the fair value of the Company's warrant liability, the fair value of which is determined by Level 3 inputs for the years ended December 31, 2012 and 2011:

Balance at December 31, 2010	\$ 1,604,742
Change in fair value	2,756,426
Balance at December 31, 2011	\$ 4,361,168
Warrants exercised	(615,859)
Change in fair value	(2,257,130)
Balance at December 31, 2012	\$ 1,488,179

**(g) LONG-LIVED ASSETS OTHER THAN GOODWILL**

Long-lived assets other than goodwill consist primarily of property and equipment and long-term investments in corporate debt securities. The aggregate balances for these long-lived assets were \$3,779,578 and \$694,624 as of December 31, 2012 and 2011, respectively. The Company applies the guidance in FASB Codification Topic 360-10-05, *Impairment or Disposal of Long-Lived Assets*. If it were determined that the carrying value of the Company's other long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, the Company would measure an impairment based on application of GAAP. The Company recognized impairment charges of \$1,000 in the year ended December 31, 2010 related to certain equipment with no current or planned future use. The Company did not recognize any impairment charges for the years ended December 31, 2012 and 2011.

Purchased equipment is recorded at cost. The Company does not currently hold any leased equipment. Depreciation and amortization are provided on the straight-line method over the estimated useful lives of the related assets or the remaining terms of the leases, whichever is shorter, as follows:

Asset Classification	Estimated Useful Life
Laboratory equipment, computers and software	3-5 years
Leasehold improvements	Lesser of life of the lease or the life of the asset
Office furniture and equipment	5 years

**(h) GOODWILL**

As of December 31, 2012 and 2011, the Company had recorded goodwill of \$8,982,000. The Company applies the guidance in the FASB Codification Topic 350, *Intangibles - Goodwill and Other*. During each of December 2012, 2011 and 2010, the Company completed its annual goodwill impairment tests and determined that the Company represented a single reporting unit and as of those dates the fair value of the Company exceeded the carrying value of its net assets. Accordingly, no goodwill impairment was recognized for the years ended December 31, 2012, 2011 and 2010.

**(i) TREASURY STOCK**

On May 31, 2002, the Company announced that its Board of Directors had approved the repurchase of up to \$3,000,000 of the Company's common stock. The Company accounts for its common stock repurchases as treasury stock under the cost method. In 2002, the Company repurchased 1,047,707 shares of its common stock at a cost of \$891,274 pursuant to this repurchase program, and the Company has not purchased any shares since 2002.



**Table of Contents****(j) BASIC AND DILUTED LOSS PER COMMON SHARE**

Basic and diluted net losses per share were determined by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share for all periods presented, as the effect of the potential common stock equivalents is antidilutive due to the Company's net loss position for all periods presented. Antidilutive securities consist of stock options and warrants outstanding as of the respective reporting period. Antidilutive securities as of December 31, 2012, 2011 and 2010 consisted of the following:

	<b>2012</b>	<b>As of December 31, 2011</b>	<b>2010</b>
Stock options outstanding	10,437,761	11,094,241	11,537,750
Warrants outstanding	1,373,517	1,610,818	1,612,322
<b>Total antidilutive securities</b>	<b>11,811,278</b>	<b>12,705,059</b>	<b>13,150,072</b>

**(k) STOCK-BASED COMPENSATION**

The Company adopted Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which established standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services, and is now referred to as the FASB Codification Topic 718, *Compensation - Stock Compensation*. Topic 718 focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. Topic 718 requires that the fair value of such equity instruments be recognized as an expense in the financial statements as services are performed.

**(l) OPERATING LEASES**

The Company currently has one facility located at 4 Maguire Road in Lexington, Massachusetts under a noncancellable operating lease agreement for office and laboratory space. The rent payments for this facility escalate over the lease term and the Company expenses its obligations under this lease agreement on a straight-line basis over the term of the lease (see Note 9).

**(m) CONCENTRATION OF RISK**

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents, marketable securities and long-term investments. The Company invests directly in commercial paper of financial institutions and corporations with A-/Aa3 or better long-term ratings and A-1/P-1 short term debt ratings and U.S. Treasury securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company's credit risk related to marketable securities and long-term investments is reduced as a result of the Company's policy to limit the amount invested in any one issue.

The Company's accounts receivable at December 31, 2012, represents amounts due from collaborators, primarily for royalties earned on sales of Erivedge by Genentech and milestones earned under the agreement with LLS.

The Company relies on third parties to supply certain raw materials necessary to produce its drug candidates, including CUDC-427, CUDC-907 and CUDC-101, for preclinical studies and clinical trials. There are a small number of suppliers for certain raw materials that the Company uses to manufacture its drug candidates.

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(n) **COMPREHENSIVE LOSS**

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes unrealized holding gains and losses arising during the period on available-for-sale securities that are not other-than-temporarily impaired.

(o) **NEW ACCOUNTING PRONOUNCEMENTS**

In July 2012, the Financial Accounting Standards Board issued amended accounting guidance for testing indefinite-lived intangible assets for impairment. The amendments permit a company to first assess the qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the indefinite-lived intangible asset is impaired. The more-likely-than-not threshold is defined as having a likelihood of more than 50 percent. If, after assessing the totality of events or circumstances, a company concludes it is more likely than not that the fair value of the indefinite-lived intangible asset exceeds its carrying value, then the company is not required to take further action. A company also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. A company will be able to resume performing the qualitative assessment in any subsequent period. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. The Company does not expect the adoption to have any impact on its consolidated financial statements.

In February 2013, the FASB issued amended accounting guidance for reporting accumulated other comprehensive income. The amendments require a company to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, a company is required to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income, a company is required to cross-reference to other disclosures required under U.S. GAAP that provide additional detail about those amounts. The amendments are effective prospectively for reporting periods beginning after December 15, 2012. Other than a change in presentation, the adoption of this guidance is not expected to have an impact on the Company's consolidated financial statements.

**(3) RESEARCH AND DEVELOPMENT COLLABORATIONS**

(a) **GENENTECH, INC. JUNE 2003 COLLABORATION**

(i) *Agreement Summary*

In June 2003, the Company licensed its proprietary Hedgehog pathway technologies to Genentech for human therapeutic use. The primary focus of the collaborative research plan has been to develop molecules that inhibit the Hedgehog pathway for the treatment of various cancers. The collaboration is currently focused on the development of Erivedge (vismodegib/GDC-0449/RG3616), a small molecule Hedgehog pathway inhibitor for the treatment of certain solid tumor cancers that received FDA approval in January 2012. Genentech is currently conducting a phase II clinical trial with Erivedge in operable basal cell carcinoma and several additional clinical trials are ongoing by third parties under collaboration agreements between Genentech and the National Cancer Institute as well as Genentech and third-party investigators.

Pursuant to the agreement, Genentech made an up-front payment of \$8,500,000, which consisted of a \$3,509,000 non-refundable license fee payment and \$4,991,000 in exchange for shares of the Company's common stock. Genentech also made license maintenance fee payments totaling

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\$4,000,000 over the first two years of the collaboration and agreed to make additional contingent cash payments, assuming specified clinical development and regulatory approval objectives are met. The Company is eligible to receive up to \$115,000,000 in contingent cash payments under the collaboration for the development of Erivedge or another small molecule Hedgehog pathway inhibitor, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives, of which it has received \$46,000,000 as of December 31, 2012. The Company is eligible for payments upon regulatory marketing approvals of Erivedge in Europe and Australia, for which submissions were filed with regulatory authorities in 2011 and 2012, respectively.

In addition to these payments, the Company will receive royalties on sales of any Hedgehog pathway inhibitor products that are successfully commercialized by Genentech and Roche, including Erivedge. As it relates to Erivedge, Curis Royalty, which is 100% owned by the Company (see Note 8), is entitled to a mid- to high-single digit royalty, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to Erivedge may be decreased to a low- to mid-single digit royalty. Future royalty payments related to Erivedge will service the outstanding debt and accrued interest to BioPharma-II, up to the quarterly caps for 2013, 2014 and 2015, and until the debt is fully repaid thereafter (see Note 8).

Unless terminated earlier, the agreement shall expire six months after the later of the expiration of Genentech's obligation to pay royalties to the Company under the agreement or such time as no activities have occurred under the agreement for a period of twelve months.

*(ii) Accounting Summary*

The Company considers its June 2003 arrangement with Genentech to be a revenue arrangement with multiple deliverables. The Company's deliverables under this collaboration include an exclusive license to its Hedgehog pathway inhibitor technologies, research and development services for the first two years of the collaboration, and participation on the joint steering committee. The Company applied the provisions of the FASB Codification Topic 605-25, *Revenue Recognition, Multiple Element Arrangement* to determine whether the performance obligations under this collaboration could be accounted for separately or should be accounted for as a single unit of accounting. The Company determined that the deliverables, specifically, the license, research and development services and steering committee participation, represented a single unit of accounting because the Company believes that the license, although delivered at the inception of the arrangement, did not have stand-alone value to Genentech without the Company's research and development services and steering committee participation. In addition, objective and reliable evidence of the fair value of the Company's research and development services and steering committee participation could not be determined. During 2007, the Company reassessed its participation on the joint steering committee and concluded that its participation in the joint steering committee had become inconsequential and perfunctory. As a result, the Company determined that it had no further performance obligations under this collaboration; therefore, future consideration received from Genentech would be recognized in the Company's financial statements in the period in which it was earned.

The Company received payments from Genentech totaling \$14,000,000 during each of the years ended December 31, 2012 and 2011, respectively, for the achievement of certain clinical development objectives related to Erivedge described above. The Company has recorded these amounts as revenue within *License Fees* in the Revenues section of its Consolidated Statement of Operations for the years ended December 31, 2012 and 2011, respectively. The Company did not receive any such payments for the year ended December 31, 2010.

As a result of its licensing agreements with various universities, the Company is obligated to make payments to these university licensors when certain payments are received from Genentech. As of December 31, 2012, the Company has incurred aggregate expenses over the term of this collaboration of \$3,714,000 in connection with its receipt of cash payments from Genentech for research, development and regulatory objectives achieved related to such university licensing agreements. In



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connection with the receipt of payments from Genentech, the Company recorded research and development expenses of \$2,114,000 during the year ended December 31, 2012, which represents the Company's obligations to these university licensors. Of this amount, the Company recognized expense of \$964,000, which represents the fair value of a one-time issuance of an aggregate of 200,000 shares of the Company's common stock in March 2012 to two university licensors in connection with the FDA-approval of Erivedge in January 2012. In addition, the Company recorded research and development expenses of \$650,000 for obligations the Company incurred in connection with Roche's filing in 2009 of an investigational new drug application in Australia, its application to the TGA for marketing registration of Erivedge in Australia and the related \$4,000,000 milestone that the Company received. The remaining expense recognized of \$500,000 relates to the Company's receipt of the \$10,000,000 milestone payment associated with the FDA's U.S. approval of Erivedge in January 2012. During the year ended December 31, 2011, the Company recorded research and development expenses of \$700,000 representing 5% of the \$14,000,000 in cash payments received during 2011.

In addition, the Company recognized \$1,529,644 in royalty revenue from Genentech's net sales of Erivedge during the year ended December 31, 2012. The Company also recorded cost of royalty revenues within the costs and expenses section of its Consolidated Statements of Operations of \$176,482 during this same period, which represents 5% of the royalties earned by the Company with respect to Erivedge that the Company is obligated to pay to university licensors plus a one-time cash payment of \$100,000 paid to one university licensor upon the first commercial sale of Erivedge for the year ended December 31, 2012.

During the years ended December 31, 2012, 2011 and 2010, the Company also recorded Research and development revenue of \$363,000, \$388,000 and \$275,000, respectively, related to expenses incurred on behalf of Genentech that were paid by the Company and for which Genentech is obligated to reimburse the Company. The Company will continue to recognize revenue for expense reimbursement as such reimbursable expenses are incurred, provided that the provisions of the FASB Codification Topic 605-45 are met.

The Company had recorded \$622,000, of which \$559,870 relates to Erivedge royalties earned in the fourth quarter of 2012, and \$24,000, as of December 31, 2012 and 2011, respectively, as amounts receivable from Genentech under this collaboration in Accounts receivable in the Company's Current Assets section of its Consolidated Balance Sheets.

**(b) IAP LICENSE AGREEMENT WITH GENENTECH, INC.**

On November 27, 2012, the Company entered into an exclusive license agreement, or the IAP license agreement, with Genentech, pursuant to which Genentech granted to the Company an exclusive, worldwide license to develop and commercialize GDC-0917, a small molecule that is designed to promote cancer cell death by antagonizing inhibitor of apoptosis proteins, or IAPs. The Company has designated GDC-0917 as CUDC-427.

Pursuant to the terms of the IAP license agreement, Genentech has agreed to transfer to the Company know how, information and materials necessary to continue the development of CUDC-427. Genentech will also assign its existing investigational new drug application, or IND, for CUDC-427 to the Company.

Under the terms of the agreement, the Company has agreed to use commercially reasonable efforts to develop and commercialize CUDC-427, including to conduct at least one additional phase I clinical trial of CUDC-427, and unless the results of the additional phase I trial do not provide sufficient scientific or clinical justification for continued clinical development, to conduct a phase II clinical trial to inform a decision to start a phase III clinical trial. The Company will be solely responsible for all future costs related to the development, registration and commercialization of products under the agreement.

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Given that the compound licensed from Genentech is in clinical development and will require substantial completion of development, regulatory and marketing approval efforts in order to reach technological feasibility, the Company recognized in-process research and development expense of \$9,500,000 related to the up-front license fee and technology transfer costs within the 2012 Consolidated Statement of Operations. As of December 31, 2012, the Company had recorded \$500,000 as amounts payable to Genentech under this collaboration in Accounts payable in the Company's Current Liabilities section of its Consolidated Balance Sheets.

In addition, Genentech is eligible to receive milestone payments upon the first commercial sale of products containing CUDC-427 in certain territories, and escalating royalties on net sales of products, which royalties are subject to reduction in certain limited circumstances. On a product-by-product and country-by-country basis, the term of the Company's royalty payment obligations will begin on the first commercial sale of a product in a country and will continue until the later of (i) 10 years after the first commercial sale of such product in such country and (ii) the date of expiration of Genentech's patent rights covering such product in such country. Upon expiration of its royalty payment obligations with respect to a product in a country, the Company's license with respect to such product in such country will become royalty-free and fully paid-up.

The IAP license agreement will continue in effect until expiration of all royalty payment obligations with respect to any product, unless terminated early by either party as described below. Upon expiration of the agreement, the Company's license will become royalty-free, fully paid-up, irrevocable and perpetual.

Each of Genentech and the Company may terminate the IAP license agreement prior to expiration in the event of the uncured material breach of the agreement by the other party. In addition, the Company may terminate the IAP license agreement prior to expiration for any reason upon 90 days' prior written notice to Genentech. Upon any termination of the IAP license agreement, the license granted to the Company will terminate and revert to Genentech. If Genentech terminates the IAP license agreement for an uncured material breach by the Company, or if the Company terminates the agreement for any reason other than uncured material breach by Genentech, Genentech will be entitled to certain licenses and other rights with respect to products existing as of the date of termination, and the Company may, under specified circumstances, be obligated to supply products to Genentech for a limited period after termination.

(c) THE LEUKEMIA & LYMPHOMA SOCIETY AGREEMENT

(i) *Agreement Summary*

In November 2011, the Company entered into an agreement under which The Leukemia & Lymphoma Society (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 will make milestone payments up to \$4,000,000 that are contingent upon the Company's achievement of specified clinical development objectives with CUDC-907.

In the fourth quarter of 2012, the Company earned the following milestone payments under the agreement as it relates to CUDC-907 as follows:

\$500,000 upon the Company's receipt of approval from an LLS oversight committee regarding the outcome of the Company's pre-IND correspondence with FDA;

\$250,000 upon the Company's filing of an IND with the FDA and

\$250,000 upon the first IRB approval for the initiation of a phase I trial.

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In January 2013, the Company achieved an additional milestone payments under the LLS agreement of \$100,000 related to treatment of the first patient in the phase I clinical trial of CUDC-907. Additional milestone payments may be earned assuming CUDC-907 continues to progress through the phase I clinical trial.

Under certain conditions associated with the successful partnering and/or commercialization of CUDC-907 in the specified indications, the Company may be obligated to make payments, including royalties, to LLS up to a maximum of \$10,000,000. This obligation is limited to 2.5 times the amount the Company receives from LLS, and, as of December 31, 2012, the maximum obligation, assuming that CUDC-907 successfully progresses through future clinical trials, would be \$2,500,000. If clinical development of 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. As of December 31, 2012 the Company has not recorded an obligation to repay any of the funds received from LLS because the contingent repayment obligation depends solely on the successful results of the continued development of CUDC-907, which is not probable at December 31, 2012 as this program remains in the very early stages of clinical development.

The LLS agreement also stipulates a follow-up diligence period beginning on the date the Company receives its last milestone payment from LLS and ends on the earlier of (a) five years from that date or (b) the fulfillment (or termination, as applicable) of Company's payment obligations as described above. During the follow-up period, the Company agrees that it will take the appropriate steps as are commercially reasonable to further the clinical and commercial development of CUDC-907 in the defined field in at least one major market, provided that the Company reasonably believes that CUDC-907 is safe and effective in the field as determined by successfully meeting its pre-determined endpoints in its clinical trials, and further provided that the Company receives necessary regulatory guidance from agency officials in the applicable major market(s) to continue development and reach the market for CUDC-907 in the defined field. If the program is successful as defined by the agreement, and if Curis cannot fund the additional clinical development, the Company agrees to seek to license CUDC-907 to a third party, either on its own or through LLS, in the defined field in the same commercially reasonable manner during the remainder of the follow-up period. The Company will be solely responsible for all costs related to the development, registration and commercialization of products under the agreement.

The agreement became effective on November 29, 2011 and will remain in effect until the completion of the defined milestones, unless earlier terminated in accordance with the provisions of the agreement, including safety issues related to the administration of CUDC-907, failure to obtain or maintain regulatory approvals for clinical trials, and breach by either party.

*(ii) Accounting Summary*

The Company considers its agreement with LLS to be a revenue arrangement with multiple deliverables. The Company's obligations under this agreement include: (i) conduct the development program through a phase Ib/IIa clinical trial; (ii) participate on the joint research advisory committee; and (iii) continue development during a follow-up diligence period of five years, if CUDC-907 is successful, as described above. The Company determined that the LLS arrangement is an obligation to perform contractual services and that payments received from LLS should be recognized as revenue rather than contra-research and development expenses or other income because this arrangement is part of the Company's on-going operations as it relates to one of its three internal proprietary programs and the arrangement is similar to other types of arrangements the Company has entered into historically.

The follow-up diligence period becomes an obligation only if and when CUDC-907 has successful results from the completion of a phase Ib/IIa study and has received the appropriate regulatory approvals to proceed with additional clinical testing. The Company initiated a phase I study of

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CUDC-907 in December 2012 and treated the first patient with CUDC-907 in January 2013. Since the Company's intention would be to continue to develop CUDC-907 upon completion of a successful program, either internally or through a licensee, it has determined that there is no commercial substance to the follow-up diligence period, which is also based on the same level of success of the program. As a result, the Company determined that the follow-up diligence period is a non-substantive obligation as: (i) this performance obligation is not essential to the current development of CUDC-907 as the Company is only eligible to receive funding if specified clinical development milestones are achieved; and (ii) any repayment right only exists if the program is successful beyond phase Ib/IIa and the Company breaches this obligation by choosing not to use reasonable effort to continue developing CUDC-907, which is not probable at December 31, 2012.

The Company believes that its participation on the joint research advisory committee, which is comprised of equal representation from Curis and LLS, is tied to its performance to conduct the research program and is occurring concurrent with the research and development services. The Company determined that its participation on the joint research advisory committee does not have stand-alone value and is essential to the development of CUDC-907 since the Company has the sole responsibility for the development program. The Company determined that the only substantive deliverables are limited to the research and development services and joint research advisory committee participation, represented a single unit of accounting.

The Company applied the provisions of ASC 605-28, *Revenue Recognition, Milestone Method* to determine whether the revenue earned under this agreement should be accounted for as substantive milestones. In determining whether the milestones in this arrangement are substantive, the Company considered whether uncertainty exists as to: (i) the achievement of the milestone event at the inception of the arrangement; (ii) the achievement of the milestone involves substantive effort and can only be achieved based in whole or part on the performance or the occurrence of a specific outcome resulting from the Company's performance; (iii) the amount of the milestone payment appears reasonable either in relation to the effort expected to be expended or to the projected enhancement of the value of the delivered items; (iv) there is any future performance required to earn the milestone; and (v) the consideration is reasonable relative to all deliverables and payment terms in the arrangement. When a substantive milestone is achieved, the accounting guidance permits recognition of revenue related to the milestone payment in its entirety. The Company determined that the milestones achieved in 2012 under the LLS agreement were substantive and recorded the related revenue totaling \$1,000,000 in the year ended December 31, 2012.

As of December 31, 2012, the Company had recorded \$250,000 as amounts receivable from LLS under this collaboration in Accounts receivable in the Company's Current Assets section of its Consolidated Balance Sheets.

(d) DEBIOPHARM AUGUST 2009 LICENSE AGREEMENT

(i) *Agreement Summary*

In August 2009, the Company entered into a license agreement with Debiopharm, pursuant to which the Company has granted to Debiopharm a worldwide, exclusive royalty-bearing license, with the right to grant sublicenses, to develop, manufacture, market and sell any product containing Curis' HSP90 inhibitor technology, including its lead HSP90 compound under development, CUDC-305, which Debiopharm has since renamed Debio 0932. Debiopharm has assumed all future development responsibility and all future costs related to the development, registration and commercialization of products under the agreement.

Pursuant to the terms of the agreement, the Company used its reasonable commercial efforts to transfer to Debiopharm know how, information and clinical materials necessary for Debiopharm to continue the development of products in accordance with the development plan outlined in the agreement, all of which were completed as of December 31, 2009. Furthermore, at no cost to Debiopharm, the Company provided a reasonable amount of technical, scientific and intellectual property support to the development plan, as requested by Debiopharm, during the first six months of the agreement.

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Pursuant to the terms of the agreement, Debiopharm has agreed to undertake reasonable commercial efforts to implement the development plan in the timeframes described in the agreement in order to develop, register and commercialize the product in specified markets and will be solely responsible for all the costs relating thereto. Debiopharm will retain final decision making authority on all development, commercialization, marketing, manufacturing and regulatory matters relating to the product.

As consideration for the exclusive license rights provided in the agreement, and subject to the terms of the agreement, Debiopharm has agreed to pay the Company up to an aggregate of \$90,000,000 assuming the successful achievement of specified clinical development and regulatory approval objectives. Of this amount, the Company has received \$13,000,000 under this agreement. In addition, Debiopharm will pay the Company:

a specified percentage of all sublicensing payments received by Debiopharm and its affiliates from sublicensees;

a specified percentage of royalties Debiopharm and its affiliates receive from sublicensees; and

a specified percentage of royalties on net sales of products by Debiopharm or its affiliates.

The agreement was effective as of August 5, 2009, and unless terminated earlier will expire, on a country-by-country basis, on the later of (i) the expiration of the last-to-expire valid claim of the Company's patents and joint patents relating to the products, and (ii) the 10<sup>th</sup> anniversary of the first commercial sale of the product in such country. Pursuant to the agreement, either party can terminate the agreement upon notice under prescribed circumstances, and the agreement specifies the consequences to each party for such early termination.

(ii) *Accounting Summary*

The Company considers its arrangement with Debiopharm to be a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under this collaboration included an exclusive license to its HSP90 inhibitor technologies, a reasonable amount of technical, scientific and intellectual property support to the development plan, as requested by Debiopharm, during the first six months of the agreement and participation on a steering committee for which the Company received a \$2,000,000 up-front, nonrefundable license fee. The Company applied the provisions of the FASB Codification Topic 605-25, *Revenue Recognition, Multiple Element Arrangements*, to determine whether the performance obligations under this collaboration could be accounted for separately or as a single unit or multiple units of accounting. The Company determined that these performance obligations represented a single unit of accounting, since, initially, the license does not have stand-alone value to Debiopharm without the Company's technical expertise and steering committee participation during the initial six-month period. In addition, objective and reliable evidence of the fair value of the Company's technical support and steering committee participation could not be determined.

At the time the agreement was entered into, the Company's ongoing substantive performance obligations under this collaboration consisted of support to Debiopharm during the initial six months of the agreement and participation on a joint steering committee. The Company has estimated that its participation on the joint steering committee should only factor into the performance period as it relates to the six-month period in which the Company has a participatory role. Because the Company estimated that its level of effort would be consistent over the six-month term of the arrangement, the Company accounted for the arrangement under the proportional performance method.

The \$2,000,000 up-front fee was recognized ratably as the research and joint steering committee services were provided over the estimated six-month performance period, through January 2010, at a rate of \$333,000 per month. During the year ended December 31, 2010, the Company recorded revenue of \$333,000 related to the Company's efforts under the Debiopharm arrangement, which was recorded in License Fees in the Company's Revenues section of its Consolidated Statement of Operations.

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The Company believes that contingent payments tied to preclinical, clinical development and drug approval objectives under this collaboration would not constitute substantive milestones since the successful achievement of these objectives would not meet each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones. For any contingent payments received by the Company subsequent to the conclusion of the performance period in January 2010, the Company would have no future deliverables under the agreement, and the Company would recognize such contingent payments as revenue at the time when the objectives are met and payable. The Company earned \$8,000,000 under this agreement in March 2010 upon acceptance by French regulatory authorities of Debiopharm's clinical trial application for Debio 0932, and \$3,000,000 in July 2010 upon Debiopharm's treatment of the fifth patient in its phase I clinical trial. The Company recorded \$11,000,000 as revenue within License Fees in the Revenues section of its Consolidated Statement of Operations for the year ended December 31, 2010 because the Company had no ongoing material performance obligations under the agreement. The Company did not receive any such payments for the years ended December 31, 2012 and 2011.

**(4) FORMER LICENSEES AND COLLABORATIONS**

**(a) MICROMET SETTLEMENT**

On February 4, 2010, the Company entered into a settlement, mutual release and termination agreement with Micromet, Inc. to resolve a claim filed by the Company relating to a June 2001 license agreement between the Company and Micromet's wholly owned subsidiary, Micromet AG, associated with the Company's single chain peptide technology. Under the June 2001 agreement, Micromet AG acquired from the Company certain intellectual property assets relating to single chain antibodies, including patents and license agreements. Pursuant to the settlement agreement, Micromet made a final payment of \$4,000,000 during the first quarter of 2010 to the Company in order to settle the dispute and discharge and terminate all future payment obligations that would have arisen under the June 2001 Agreement. The Company has recorded the \$4,000,000 within the License fee revenue line item in the Consolidated Statement of Operations for the year ended December 31, 2010. During the first quarter of 2010, the Company incurred approximately \$1,526,000 in legal fees and expenses through the settlement date. These costs are included within the General and Administrative expense line item of the Consolidated Statement of Operations for the respective periods.

**(5) STOCK PLANS AND STOCK BASED COMPENSATION**

As of December 31, 2012, the Company had two shareholder-approved, share-based compensation plans: the 2010 Stock Incentive Plan and the 2010 Employee Stock Purchase Plan. These plans were adopted by the board of directors in April 2010 and approved by shareholders in June 2010 as described below. In the first quarter of 2010, the Company's 2000 Stock Incentive Plan expired in accordance with its terms and its 2000 Director Stock Option Plan had no available shares remaining under the plan. No additional awards will be made under these plans, although all outstanding awards under these plans will remain in effect until they are exercised or they expire in accordance with their terms.

**2010 Stock Incentive Plan**

In April 2010, the board of directors adopted and, in June 2010, the stockholders approved, the 2010 Stock Incentive Plan, which permits the granting of incentive and non-qualified stock options and stock awards to employees, officers, directors, and consultants of the Company and its subsidiaries at prices determined by the Company's board of directors. The Company can issue up to 6,000,000 shares of its common stock pursuant to awards granted under the 2010 Stock Incentive Plan. Options become exercisable as determined by the board of directors and expire up to 10 years from the date of grant.

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The 2010 Stock Incentive Plan uses a fungible share concept under which each share of stock subject to awards granted as options and stock appreciation rights will cause one share per share under the award to be removed from the available share pool, while each share of stock subject to awards granted as restricted stock, restricted stock units, other stock-based awards or performance awards where the price charged for the award is less than 100% of the fair market value of the Company's common stock will cause 1.22 shares per share under the award to be removed from the available share pool. As of December 31, 2012, the Company had only granted options to purchase shares of the Company's common stock with an exercise price equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the grant date. As of December 31, 2012, 2,765,750 shares remained available for grant under the 2010 Stock Incentive Plan.

During the year ended December 31, 2012, the Company's board of directors granted options to purchase 1,182,000 shares of the Company's common stock to officers and employees of the Company under the 2010 Stock Incentive Plan. These options vest over a four-year period and bear exercise prices that are equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the respective grant dates.

During the year ended December 31, 2012, the Company's board of directors also granted options to its non-employee directors to purchase 470,000 shares of common stock under the 2010 Stock Incentive Plan. These options will vest monthly over a one-year period and bear exercise prices that are equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the grant date.

**Employee and Director Grants**

In determining the fair value of stock options, the Company uses the Black-Scholes option pricing model. The Black-Scholes option pricing model employs the following key assumptions for employee option grants issued in each of the following years:

	<b>For the Year Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Expected term (years) Employees	6.0	6.0	6.0
Expected term (years) Directors	6.0	6.0	6.0
Risk-free interest rate	1.0-1.2%	1.2-2.5%	2.3-2.8%
Expected volatility	74-76%	73-76%	69-73%
Expected dividend yield	None	None	None

The expected volatility is based on the annualized daily historical volatility of the Company's stock price through the end of the reporting period 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 volatility of the stock price. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the expected term of the respective grant. The Company does not anticipate declaring 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.

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At December 31, 2012, the aggregate intrinsic value of employee options outstanding was \$11,895,000, of which \$10,994,000 related to exercisable options, and the weighted average remaining contractual life of vested stock options was 4.14 years. The weighted average grant-date fair values of stock options granted during the years ended December 31, 2012, 2011 and 2010 were \$2.99, \$1.72 and \$1.46, respectively. As of December 31, 2012, there was approximately \$4,099,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding under the Company's 2000 and 2010 Stock Incentive Plans that is expected to be recognized as expense over a weighted average period of 2.5 years. The intrinsic value of employee stock options exercised during the years ended December 31, 2012, 2011 and 2010 were \$6,415,000, \$2,129,000 and \$154,000, respectively. The total fair value of vested stock options for the years ended December 31, 2012, 2011 and 2010 were \$2,525,000, \$1,504,000 and \$2,219,000, respectively.

**Non-Employee Grants**

The Company has periodically granted stock options and unrestricted stock awards to consultants for services. Should the Company or the consultant terminate the consulting agreement, any unvested options will be cancelled. Unvested non-employee options are marked-to-market, which means that as the Company's stock price fluctuates, the related expense either increases or decreases. The Company recognized expense of \$355,222 and \$130,281 related to non-employee stock options and stock awards for the years ended December 31, 2012 and 2011, respectively. The Company reversed expense of \$11,968 related to non-employee stock options and stock awards for the years ended December 31, 2010.

A summary of stock option activity under 2010 Stock Incentive Plan, the 2000 Stock Incentive Plan and the 2000 Director Stock Option Plan is summarized as follows:

	Number of Shares	Weighted Average Exercise Price per Share
Outstanding, December 31, 2011 (8,888,033 exercisable at weighted average price of \$2.06 per share)	11,094,240	\$ 2.13
Granted	1,652,000	4.52
Exercised	(2,193,666)	1.69
Cancelled	(114,813)	2.66
Outstanding, December 31, 2012 (8,134,191 exercisable at weighted average price of \$2.30 per share)	10,437,761	\$ 2.59
Vested and unvested expected to vest	10,416,097	\$ 2.59



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The table below summarizes options outstanding and exercisable at December 31, 2012:

Exercise Price Range	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price per Share	Number of Shares	Weighted Average Exercise Price per Share
\$0.79 - \$ 1.39	2,568,747	4.70	\$ 1.19	2,521,395	\$ 1.19
1.43 - 2.15	2,564,418	5.10	1.73	2,122,159	1.64
2.27 - 3.76	2,407,982	4.50	2.75	1,785,192	2.60
3.98 - 4.52	2,176,614	7.32	4.38	993,445	4.22
4.56 - 5.60	720,000	1.37	4.74	712,000	4.74
	10,437,761	5.07	\$ 2.59	8,134,191	\$ 2.30

**2010 Employee Stock Purchase Plan**

In April 2010, the board of directors adopted and, in June 2010, the stockholders approved, the 2010 Employee Stock Purchase Plan, or the ESPP. The Company has reserved 500,000 of its shares of common stock for issuance under the ESPP. Eligible employees may purchase shares of the Company's common stock at 85% of the lower closing market price of the common stock at the beginning or ending date of the purchase period, as defined. The Company has two six-month purchase periods per year. As of December 31, 2012, 221,116 shares were issued under the ESPP, of which 58,282 were issued during 2012. As of December 31, 2012, there were 278,884 shares available for future purchase under the ESPP.

For the years ended December 31, 2012, 2011 and 2010, the Company recorded compensation expense related to its ESPP and calculated the fair value of shares expected to be purchased under the ESPP using the Black-Scholes models with the following assumptions:

	For the Year Ended December 31,		
	2012	2011	2010
Compensation expense recognized under ESPP	\$ 72,833	\$ 94,529	\$ 51,000
Expected term	6 months	6 months	6 months
Risk-free interest rate	0.05-0.15%	0.1-0.2%	0-0.2%
Volatility	42-75%	75-85%	85-120%
Dividends	None	None	None

Stock-based compensation for employee and director stock option grants for the years ended December 31, 2012, 2011 and 2010 of \$3,268,689, \$1,641,830 and \$1,979,090, respectively, was calculated using the above valuation models and has been included in the Company's results of operations.

**Total Stock-Based Compensation Expense**

For the years ended December 31, 2012, 2011 and 2010, 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 and Comprehensive Loss:

	For the Year Ended December 31,		
	2012	2011	2010
Research and development expenses	\$ 1,075,134	\$ 723,634	\$ 663,286
General and administrative expenses	2,548,777	1,048,477	1,303,836
Total stock-based compensation expense	\$ 3,623,911	\$ 1,772,111	\$ 1,967,122



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No income tax benefits have been recorded for the years ended December 31, 2012, 2011 or 2010, as the Company has recorded a full valuation allowance and management has concluded that it is more likely than not that the net deferred tax assets will not be realized (see Note 11).

**(6) PROPERTY AND EQUIPMENT**

Property and equipment consist of the following:

	December 31,	
	2012	2011
Laboratory equipment, computers and software	\$ 2,167,794	\$ 2,503,832
Leasehold improvements	62,621	62,621
Office furniture and equipment	304,590	281,445
	2,535,005	2,847,898
Less Accumulated depreciation and amortization	(2,100,837)	(2,392,168)
Total	\$ 434,168	\$ 455,730

The Company recorded depreciation and amortization expense of \$126,537, \$107,396 and \$686,495 for the years ended December 31, 2012, 2011 and 2010, respectively.

During the years ended December 31, 2012 and 2011, the Company identified certain of its fully depreciated assets that were no longer being used. As a result, the Company wrote off gross assets and related accumulated depreciation, totaling \$418,000 for each of the years ended December 31, 2012 and 2011, respectively.

**(7) ACCRUED LIABILITIES**

Accrued liabilities consist of the following:

	December 31,	
	2012	2011
Accrued compensation	\$ 999,038	\$ 1,065,570
Professional fees	127,500	190,500
Accrued interest on debt (see Note 8)	204,167	
Other	143,851	166,037
Total	\$ 1,474,556	\$ 1,422,107

**(8) DEBT**

In December 2012, the Company, through its wholly-owned subsidiary, Curis Royalty, entered into a \$30,000,000 debt transaction at an annual interest rate of 12.25% collateralized with certain future Erivedge royalty and royalty-related payment streams with BioPharma-II. Under the terms of the loan, quarterly royalty payments from Genentech will first be applied to pay (i) escrow fees payable by the Company pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) the Company's 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 the Company enforcing its right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject

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to caps of \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$3,000,000 per quarter in 2015, will be applied first, to pay interest and second, principal on the loan. The Company will be entitled to receive the

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remaining amounts above the caps, if any, and remains entitled to receive any contingent payments upon achievement of clinical development objectives. The Company retains its right to royalty payments related to sales of Erivedge following repayment of the loan.

Upon the closing of the transaction, the Company transferred to Curis Royalty, pursuant to a purchase and sale agreement between Curis and Curis Royalty, the right to receive Erivedge royalty and royalty-related payments due from Genentech as defined in the credit agreement, and BioPharma-II loaned to Curis Royalty \$30,000,000 that, together with accrued interest, will be repaid by Curis Royalty quarterly from the proceeds of these Erivedge royalty and royalty-related payments. The final maturity date of the loan will be the earlier of the date when the principal is paid in full and 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.

The credit agreement contains covenants applicable to the Company and Curis Royalty, including certain visitation, information and audits rights granted to BioPharma-II and restrictions on the conduct of business, including as it relates to continued compliance with the collaboration agreement with Genentech and specified affirmative actions regarding the escrow account set up through the escrow agreement. The credit agreement also contains further covenants solely applicable to Curis Royalty, including restrictions on incurring indebtedness, creating or granting liens, making acquisitions and making specified restricted payments.

In connection with the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) 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 payments. The loan constitutes an obligation of Curis Royalty, and is non-recourse to the Company.

As of December 31, 2012, the Company had long-term debt of \$29,838,925 (net of issuance costs of \$161,075) and recorded accrued interest of \$204,167 within its accrued liabilities section of its Consolidated Balance Sheets related to the loan. Because repayment of the loan is contingent upon the level of Erivedge royalties received, subject to certain quarterly caps, 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. Currently, the Company estimates that the debt will be repaid in early 2017. At December 31, 2012, the fair value of the principal portion of the debt is estimated to approximate the carrying value. Due to the assumptions required in estimating future Erivedge royalties and the expected repayment period, determining the fair value of the debt in subsequent reporting periods will require application of Level 3 inputs.

For the year ended December 31, 2012, the Company incurred debt issuance costs totaling \$421,715 in connection with its Erivedge royalty financing transaction, of which \$215,000 related to expenses that the Company paid on behalf of BioPharma-II and the remaining \$206,715 were incurred directly by the Company. The direct costs incurred by the Company were capitalized as assets and those costs paid on behalf of BioPharma-II have been netted against the debt on the Company's Consolidated Balance Sheet as of December 31, 2012. All issuance costs will be amortized over the estimated term of the debt using the straight-line method which approximates the effective interest method. The assumptions used in determining the expected repayment term of the debt and amortization period of the issuance costs requires management to make estimates that could impact the Company's short- and long-term classification of these costs, as well as the period over which these costs will be amortized.

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Future payments of principal on the loan will require application of the same assumptions described above and will be used to estimate short- and long-term classification of the debt within the Company's consolidated balance sheets. At December 31, 2012, the Company estimates that its future payments of principal on the loan are as follows:

	<b>Principal</b>
2013	\$
2014	3,247,924
2015	8,447,494
2016	15,682,724
2017	2,621,858
 Total payments	 30,000,000
 Less current portion	
 Total long-term debt obligations	 \$ 30,000,000

**(9) COMMITMENTS****(a) OPERATING LEASES**

Effective September 16, 2010, the Company entered into a lease agreement with the Trustees of Lexington Office Realty Trust pursuant to which the Company agreed to lease 24,529 square feet of property to be used for office, research and laboratory located at 4 Maguire Road in Lexington, Massachusetts. The Company lease for its prior headquarters at 45 Moulton Street, Cambridge, Massachusetts expired on December 31, 2010.

The term of the 4 Maguire Road lease agreement commenced on December 1, 2010, and expires on January 31, 2018. The Company has the option to extend the term for one additional five-year period upon the Company's written notice to the lessor at least one year and no more than 18 months in advance of the extension.

The total cash obligation for the base rent over the initial term of the lease agreement is approximately \$4,401,000. In addition to the base rent, the Company is also responsible for its share of operating expenses and real estate taxes, in accordance with the terms of the lease agreement. The Company has provided a security deposit to the lessor in the form of an irrevocable letter of credit in the original amount of \$277,546, which was reduced to \$235,914 during 2011 and then to \$194,282 during 2012 in accordance with the terms of the Company's lease. These amounts have been classified as the restricted investments in the Company's Consolidated Balance Sheet as of December 31, 2012 and 2011. The security deposit may be reduced by up to an additional \$41,632 over time in accordance with the terms of the lease agreement. The lessor paid \$789,000 for certain upgrades and repairs that were made to the leased property prior to the commencement date. The Company has not recognized these improvements as its assets.

If the Company is considered in default under the terms of the lease agreement and fails to cure such default in the applicable time period, the lessor may terminate the lease agreement and the Company will be required to pay the difference between the remaining rent payments through the expiration of the lease agreement and any rental income from reletting the leased property over such time period, after deducting any expenses incurred in connection with such reletting. Circumstances which may be considered a default under the lease agreement include the failure to timely pay any rent obligations and the filing by the Company of a petition for liquidation or reorganization under bankruptcy law.

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The Company's remaining operating lease commitments for all leased facilities with an initial or remaining term of at least one year are as follows:

<b>Year Ending December 31,</b>	
2013	602,000
2014	627,000
2015	651,000
2016	676,000
2017	700,000
Thereafter	59,000
<b>Total minimum payments</b>	<b>\$ 3,315,000</b>

Rent expense for all operating leases was \$614,000, \$614,000 and \$827,000 for the years ended December 31, 2012, 2011 and 2010, respectively.

**(b) LICENSE AGREEMENTS**

In exchange for the right to use licensed technology in its research and development efforts, the Company has entered into various license agreements. These agreements generally stipulate that the Company pay an annual license fee and is obligated to pay royalties on future revenues, if any, resulting from use of the underlying licensed technology. Such revenues may include, for example, up-front license fees, contingent payments upon collaborators' achievement of development and regulatory objectives, and royalties. In addition, some of the agreements commit the Company to make contractually defined payments upon the attainment of scientific or clinical milestones. During the year ended December 31, 2012, the Company also issued 200,000 shares of its common stock under agreements with two of its university licensors resulting in expense of \$964,000. The Company expenses these payments as incurred and expenses royalty payments as related future product sales or royalty revenues are recorded. The Company accrues expenses for scientific and clinical objectives over the period that the work required to meet the respective objective is completed, provided that the Company believes that the achievement of such objective is probable. The Company incurred license fee expenses within the Research and development line item of its Costs and expenses section of its Consolidated Statement of Operations for the years ended December 31, 2012, 2011 and 2010, of \$2,114,000, \$908,000 and \$243,000, respectively. For the year ended December 31, 2012, the Company also recognized \$176,482 as cost of royalty revenues in its Consolidated Statement of Operations related to such obligations (see Note 3(a)).

During the year ended December 31, 2012, pursuant to the IAP license agreement with Genentech, the Company also recognized expense of \$9,500,000 related to the up-front license fee and technology transfer costs within the in-process research and development expense line item of the Consolidated Statement of Operations (see Note 3(b)).

**(10) COMMON STOCK AND WARRANT LIABILITY*****2011 At Market Issuance Sales Agreement***

On June 13, 2011, the Company entered into an At Market Issuance Sales Agreement, or ATM agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which the Company may issue and sell from time to time through MLV shares of its common stock, \$0.01 par value per share, with an aggregate offering price of up to \$20,000,000. The Company or MLV may suspend or terminate the offering of common stock upon notice and subject to other conditions.

Upon delivery of a placement notice and subject to the terms and conditions of the ATM agreement, MLV may sell the common stock by methods deemed to be an at-the-market offering as defined in Rule 415 of the Securities Act of 1933, including without limitation sales made directly on The





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NASDAQ Global Market, on any other existing trading market for the common stock or through a market maker. With the Company's prior written approval, MLV may also sell the common stock by any other method permitted by law, including in privately negotiated transactions. MLV will act as sales agent on a commercially reasonable best efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of NASDAQ. The Company will pay MLV a commission equal to 3.0% of the gross sales price per share sold. The Company has agreed to provide indemnification and contribution to MLV against certain civil liabilities, including liabilities under the Securities Act. During the years ended December 31, 2012 and 2011, the Company has sold 210,879 and 104,118 shares of common stock under the ATM agreement resulting in gross proceeds of \$906,436 and \$416,965, respectively. Total offering expenses, including MLV's commission, incurred related to the ATM agreement for the years ended December 31, 2012 and 2011, were \$27,356 and \$128,155, respectively, which offset the gross proceeds.

**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 \$14,942,317 during the year ended December 31, 2010.

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, 2012, warrants to purchase 238,805 shares of the Company's common stock have been exercised. The warrants have an initial exercise price of \$3.55 per share and a five-year term. The warrants include certain protective features for the benefit of the warrant holder, including an anti-dilution adjustment clause and a possible cash-settlement option in the event of a change of control until the later to occur of (i) two years from the date of original issuance of the warrant and (ii) the date upon which Genentech or Roche submits a new drug application (NDA) for Erivedge which occurred in September 2011. As such, the cash-settlement option upon a change of control expired on January 27, 2012 and has no additional value to the warrant holders.

Due to the original terms, the warrants were deemed to be a liability and, therefore, the fair value of the warrants was recorded as a liability in the Consolidated Balance Sheets as of December 31, 2012 and 2011. The Company has estimated the fair value of the warrants using a Black-Scholes option pricing model under various probability-weighted outcomes which take into consideration the protective, but limited, cash-settlement feature of the warrants, with updated assumptions at each reporting date as detailed in the following table:

	2012	As of December 31, 2011	2010
Fair value of the warrants	\$ 1,488,179	\$ 4,361,168	\$ 1,604,742
Expected term	2.1 years	3 years	3-4 years
Risk-free interest rate	0.27%	0.4%	1-1.6%
Volatility	58%	78%	77.1-91.5%
Dividends	None	None	None

The Company recorded other expense of \$2,756,426 for the year ended December 31, 2011 and other income of \$2,257,130 and \$575,813 for the years ended December 31, 2012 and 2010, respectively, as a result of a change in the fair value of the warrant liability that was primarily due to changes in the Company's stock price during the respective reporting periods. During the year ended December 31, 2012, as a result of the exercise of warrants to purchase 237,301 shares of the Company's common stock, the warrant liability decreased by \$615,859 with an offsetting increase to additional paid-in-capital. As of December 31, 2012, warrants to purchase an aggregate of 1,373,517 shares of common stock are the only remaining warrants outstanding.

**Table of Contents****2007 Private Placement Offering**

As of December 31, 2009, the Company had warrants outstanding to purchase an aggregate of 1,742,671 shares of its common stock at an exercise price of \$1.02 per share under its August 2007 private placement, all of which had been accounted for within stockholders' equity. During the year ended December 31, 2010, the Company received proceeds of \$1,777,524 upon the exercise of all of these remaining outstanding warrants.

**(11) INCOME TAXES**

For the years ended December 31, 2012, 2011 and 2010, the Company did not record any federal or state income tax expense given its continued operating losses. The Company received federal tax grants of \$488,959 for the year ended December 31, 2010 under the Patient Protection and Affordable Care Act of 2010. The Company did not have any ongoing obligations under these awards and it does not expect to receive any future payments related to these grants. As a result, the Company recorded the proceeds as "Other income" in its Consolidated Statement of Operations for the year ended December 31, 2010. The grant proceeds were non-taxable on the federal and state level.

The provision for income taxes for continuing operations was at rates different from the U.S. federal statutory income tax rate for the following reasons:

	For the Year Ended December 31,		
	2012	2011	2010
Statutory federal income tax rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit	5.8%	5.1%	5.0%
Research and development tax credits	0.8%	5.4%	8.7%
Deferred compensation	2.1%	(0.4%)	(4.0%)
NOL expirations	(36.0%)	(17.3%)	(58.4%)
Other	(1.7%)	(1.9%)	(1.5%)
Net (decrease) increase in valuation allowance	(5.0%)	(24.9%)	16.2%
Effective income tax rate	%	%	%

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using future expected enacted rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

The principle components of the Company's deferred tax assets at December 31, 2012 and 2011, respectively are as follows:

	December 31,	
	2012	2011
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 67,737,000	\$ 70,767,000
Research and development tax credit carryforwards	10,538,000	10,661,000
Depreciation and amortization	490,000	175,000
Capitalized research and development expenditures	27,269,000	22,820,000
Impairment of investments	64,000	108,000
Stock options	2,809,000	2,433,000
Accrued expenses and other	707,000	1,823,000
Total Gross Deferred Tax Asset	109,614,000	108,787,000
Valuation Allowance	(109,614,000)	(108,787,000)

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Net Deferred Tax Asset	\$	\$
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The classification of the above deferred tax assets is as follows:

	December 31,	
	2012	2011
<b>Deferred Tax Assets:</b>		
Current deferred tax assets	\$ 42,000	\$ 45,000
Non-current deferred tax assets	109,572,000	108,742,000
Valuation Allowance	(109,614,000)	(108,787,000)
<b>Net Deferred Tax Asset</b>	<b>\$</b>	<b>\$</b>

As of December 31, 2012, the Company had federal and state net operating losses, or NOLs, of \$192,849,000 and \$41,059,000, respectively, and federal and state research and experimentation credit carryforwards of approximately \$8,385,000 and \$3,262,000, respectively, which will expire at various dates starting in 2012 through 2032. The Company had \$15,301,000 of federal net operating losses generated in 1997 and \$12,963,000 of Massachusetts net operating losses generated in 2007 that expired in 2012. As required by GAAP, the Company's management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, and has determined that it is more likely than not that the Company will not recognize the benefits of the deferred tax assets. Accordingly, a valuation allowance of approximately \$109,614,000 has been established at December 31, 2012. The benefit of deductions from the exercise of stock options is included in the NOL carryforwards. The benefit from these deductions will be recorded as a credit to additional paid-in capital if and when realized through a reduction of cash taxes.

Utilization of the NOL and research and development, or R&D, credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation because the Company continues to maintain a full valuation allowance on its NOL and R&D credit carryforwards. In addition, there could be additional ownership changes in the future, which may result in additional limitations in the utilization of the carryforward NOLs and credits, and the Company does not expect to have any taxable income for the foreseeable future.

An individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company's financial statements. At December 31, 2012 and 2011, the Company had no unrecognized tax benefits. The Company has not, as yet, conducted a study of its R&D credit carryforwards. This study may result in an adjustment to the Company's R&D credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under Topic 740. A full valuation allowance has been provided against the Company's R&D credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

The tax years 1998 through 2012 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the U.S., as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service, or IRS, or state tax authorities if they have or will be used in a future period. The Company is currently not under examination by the IRS or any other jurisdictions for any tax years. The Company recognizes both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company has not recorded any interest and penalties on any unrecognized tax benefits since its inception.

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**Table of Contents****(12) RELATED PARTY TRANSACTION***License Agreement*

Effective on February 24, 2012, the Company entered into a Drug Development Partnership and License Agreement for CU-906 and CU-908 with Guangzhou BeBetter Medicine Technology Company Ltd., or GBMT, a company organized under the laws of the People's Republic of China. Dr. Changgeng Qian, the Company's former Senior Vice President, Discovery and Preclinical Development, is the founder, owner, and legal representative of GBMT.

Pursuant to the GMBT license agreement, the Company has granted to GBMT an exclusive royalty-free license, with the right to grant sublicenses subject to certain conditions, to develop, manufacture, market and sell any product containing CU-906 or CU-908 in China, Macau, Taiwan and Hong Kong, which is referred to as the GBMT territory. The Company does not currently intend to internally develop these compounds. In addition, the Company has granted to GBMT a non-exclusive, royalty-free manufacturing license, with the right to grant sublicenses subject to certain conditions, to manufacture CU-906 or CU-908 or any product containing CU-906 or CU-908 outside of the GBMT Territory solely to import the compounds or products into the GBMT territory. Pursuant to the terms of the GMBT license agreement, the Company has retained rights, including the right to grant sublicenses, to develop, manufacture, market and sell any product containing CU-906 or CU-908 worldwide excluding the GBMT territory. The Company also has certain specified rights to any GBMT technology developed under the GMBT license agreement as well as certain specified rights to GBMT's interest in joint technology developed under the GMBT license agreement. Furthermore, the Company has a right of first negotiation to obtain a license to CU-906 or CU-908 for the GBMT territory from GBMT.

The Company has agreed to transfer to GBMT know how, information and materials necessary for GBMT to continue the development of products in accordance with the development plan outlined in the license agreement and has agreed not to assert certain Company patents against GBMT, its affiliates or sublicensee so that such party may manufacture, market and sell any product containing CU-906 or CU-908 in the GBMT territory. Furthermore, the Company will provide GBMT with up to \$400,000 in financial support for specified CU-908 pre-clinical activities related to enabling the filing by the Company of an IND with the FDA, provided that GBMT completes such CU-908 IND-enabling activities in accordance with specified criteria and delivers a U.S. IND package for CU-908 to the Company within prescribed timeframes as specified in the license agreement. All costs incurred under the license agreement will be expensed as incurred. During the year ended December 31, 2012, the Company had incurred expenses of \$133,333 under the GMBT license agreement reported within the research and development line item of the Company's Consolidated Statements of Operations and Comprehensive Loss and is reported within the accounts payable line item of the Company's Consolidated Balance Sheets as of December 31, 2012.

GBMT will assume all future development responsibility and incur all future costs related to the development, registration and commercialization of products in the GBMT territory under the GMBT license agreement. Pursuant to the terms of the GMBT license agreement, GBMT has agreed to undertake reasonable commercial efforts, and to use qualified third party service providers approved by the Company, to implement the development plan in the timeframes described in the GMBT license agreement in order to develop, register and commercialize the products in the GBMT territory and will be solely responsible for all the costs relating thereto. The Company and GBMT must agree to any changes to the development plan and such revised development plan is subject to review and approval by a joint steering committee.

Unless terminated earlier in accordance with its terms, the GMBT license agreement will expire on the later of (i) the expiration of the last-to-expire valid claim of the Company patents and the Company non-assert patents relating to the products, and (ii) such time as none of GBMT, its affiliates or sublicensees is commercializing any compound or product in the GBMT territory. Either party can

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terminate the GMBT license agreement with notice under prescribed circumstances, and the GMBT license agreement specifies the consequences to each party for such early termination.

The GMBT license agreement also sets forth customary terms regarding each party's intellectual property ownership rights, representations and warranties, indemnification obligations, confidentiality rights and obligations, and patent prosecution, maintenance, enforcement and defense rights and obligations.

*Severance Agreement*

On February 16, 2012, the Company and Dr. Qian entered into a severance agreement that became binding and effective on February 24, 2012. The severance agreement provides that, in exchange for execution and nonrevocation of a general release of claims in favor of the Company, Dr. Qian will be provided certain severance benefits, including a lump-sum payment equivalent to one-half times his base annual salary rate in effect as of his termination date. This payment was made in August 2012. As a result, the Company recognized expenses of \$137,500 related to Dr. Qian's severance during the year ended December 31, 2012 in the research and development line item of the Company's Condensed Consolidated Statement of Operations and Comprehensive Loss. The severance agreement also provides for the engagement of Dr. Qian as a consultant pursuant to the terms of a consulting agreement.

**(13) RETIREMENT SAVINGS PLAN**

The Company has a 401(k) retirement savings plan covering substantially all of the Company's employees. Matching Company contributions are at the discretion of the Board of Directors. For the years ended December 31, 2012, 2011 and 2010, the Board of Directors authorized matching contributions of \$153,000, \$145,000 and \$103,000, respectively.

**(14) SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following are selected quarterly financial data for the years ended December 31, 2012 and 2011:

	Quarter Ended			
	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012
Revenues	\$ 10,356,252	\$ 4,351,574	\$ 577,759	\$ 1,686,406
Income (loss) from operations	2,199,695	(2,426,105)	(4,960,912)	(13,432,485)
Net income (loss)	2,225,737	(2,886,452)	(3,385,004)	(12,371,188)
Net income (loss) per common share (basic)	\$ 0.03	\$ (0.04)	\$ (0.04)	\$ (0.15)
Net income (loss) per common share (diluted)	\$ 0.03	\$ (0.04)	\$ (0.04)	\$ (0.15)
Weighted average common shares (basic)	77,556,366	79,052,517	79,639,433	79,971,888
Weighted average common shares (diluted)	83,336,695	79,052,517	79,639,433	79,971,888

	Quarter Ended			
	March 31, 2011	June 30, 2011	September 30, 2011	December 31, 2011
Revenues	\$ 133,538	\$ 392,867	\$ 147,122	\$ 14,089,053
(Loss) income from operations	(5,332,310)	(4,618,965)	(4,816,335)	7,565,107
Net (loss) income	(6,800,151)	(4,914,064)	(4,206,555)	6,061,875
Net (loss) income per common share (basic)	\$ (0.09)	\$ (0.06)	\$ (0.05)	\$ 0.08
Net (loss) income per common share (diluted)	\$ (0.09)	\$ (0.06)	\$ (0.05)	\$ 0.07
Weighted average common shares (basic)	75,825,801	76,378,369	76,543,074	76,649,034
Weighted average common shares (diluted)	75,825,801	76,378,369	76,543,074	81,354,223



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The net loss amount presented above for the quarter ending December 31, 2012 includes revenues of \$1,000,000 that the Company earned under its agreement with LLS and a one-time charge of \$9,500,000 related to the November 2012 in-license agreement of CUDC-427 from Genentech.

The net income amount presented above for the quarter ending December 31, 2011 includes \$14,000,000 of license revenue recognized under the June 2003 license agreement with Genentech. Dilutive securities of 4,652,519 shares related to stock options and 52,670 shares related to warrants have been included in the weighted average common shares (diluted) for the quarter ended December 31, 2011.

In the fourth quarter of 2012, the Company determined that its previously filed 2012 Forms 10-Q contained errors within the statements of cash flows. More specifically, the proceeds from the settlement of stock option exercises totaling \$375,661 was incorrectly presented as cash flows from operating activities when such amount should have been classified as cash flows from financing activities for the three-, six- and nine-month periods in the statements of cash flows. The Company determined that the effect of the error was not material and therefore did not restate the Forms 10-Q as previously filed. The error was corrected in the fourth quarter of 2012 and is properly reflected in its Consolidated Statement of Cash Flows for the year ended December 31, 2012. The as reported and as adjusted numbers for the 2012 interim periods are presented as follows:

	<b>As Reported</b>		<b>As Adjusted</b>	
	<b>Cash flow provided by (used in)</b>		<b>Cash flow provided by (used in)</b>	
	<b>Operating</b>	<b>Financing</b>	<b>Operating</b>	<b>Financing</b>
	<b>Activities</b>	<b>Activities</b>	<b>Activities</b>	<b>Activities</b>
Three months ending March 31, 2012	4,313,157	2,900,195	3,937,496	3,275,856
Six months ending June 30, 2012	2,701,316	4,174,002	2,325,655	4,549,663
Nine months ending September 30, 2012	(1,479,271)	5,434,160	(1,854,932)	5,809,821



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**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. 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 December 31, 2012. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under 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 December 31, 2012, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective.

Management's report on internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, is included in Item 8 of this annual report on Form 10-K and is incorporated herein by reference.

*Changes in Internal Control Over Financial Reporting*

No changes in our internal control over financial reporting occurred during the fourth quarter of the fiscal year ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

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**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information concerning directors that is required by this Item 10 is set forth in our proxy statement for our 2013 annual meeting of stockholders under the headings Directors and Nominees for Director, Board Committees and Section 16(a) Beneficial Ownership Reporting Compliance, which information is incorporated herein by reference. The information concerning our code of ethics is set forth in our proxy statement under the heading Code of Business Conduct and Ethics. The name, age, and position of each of our executive officers is set forth under the heading Executive Officers of the Registrant in Part I of this Annual Report on Form 10-K, which information is incorporated herein by reference.

**ITEM 11. EXECUTIVE COMPENSATION**

Information required by this Item 11 is set forth in our proxy statement for our 2013 annual meeting of stockholders under the headings Executive and Director Compensation and Related Matters, Compensation Committee Interlocks and Insider Participation and Compensation Committee Report which information is incorporated herein by reference.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Information required by this Item 12 relating to security ownership of certain beneficial owners and management is contained in our 2013 proxy statement under the caption Security Ownership of Certain Beneficial Owners and Management and is incorporated herein by reference. Information required by this Item 12 relating to securities authorized for issuance under equity compensation plans is contained in our 2012 proxy statement under the caption Executive and Director Compensation and Related Matters Securities Authorized for Issuance Under Equity Compensation Plans and is incorporated herein by reference.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Information required by this Item 13 is set forth in our proxy statement for our 2013 annual meeting of stockholders under the headings Policies and Procedures for Related Person Transactions, Determination of Independence and Board Committees, which information is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Information required by this Item 14 is set forth in our proxy statement for our 2013 annual meeting of stockholders under the heading Independent Registered Public Accounting Firm's Fees and Other Matters, which information is incorporated herein by reference.

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**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a)(1) *Financial Statements.*

	<b>Page number in this report</b>
<b><u>Curis, Inc. and Subsidiaries</u></b>	
<u>Report of Independent Registered Public Accounting Firm</u>	75
<u>Consolidated Balance Sheets as of December 31, 2012 and 2011</u>	76
<u>Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2012, 2011 and 2010</u>	77
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2012, 2011 and 2010</u>	78
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2012, 2011 and 2010</u>	79
<u>Notes to Consolidated Financial Statements</u>	80

(a)(2) *Financial Statement Schedules.*

All schedules are omitted because they are not applicable or the required information is shown in the Financial Statement or Notes thereto.

(a)(3) *List of Exhibits.* The list of Exhibits filed as a part of this annual report on Form 10-K is set forth on the Exhibit Index immediately preceding such Exhibits, and is incorporated herein by reference.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CURIS, INC.

By: */s/ DANIEL R. PASSERI*  
**Daniel R. Passeri**

**Chief Executive Officer**

Date: March 13, 2013

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/ DANIEL R. PASSERI</i> <b>Daniel R. Passeri</b>	Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2013
<i>/s/ MICHAEL P. GRAY</i> <b>Michael P. Gray</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2013
<i>/s/ JAMES R. McNAB, JR.</i> <b>James R. McNab, Jr.</b>	Chairman of the Board of Directors	March 13, 2013
<i>/s/ SUSAN B. BAYH</i> <b>Susan B. Bayh</b>	Director	March 13, 2013
<i>/s/ MARTYN D. GREENACRE</i> <b>Martyn D. Greenacre</b>	Director	March 13, 2013
<i>/s/ KENNETH I. KAITIN</i> <b>Kenneth I. Kaitin</b>	Director	March 13, 2013
<i>/s/ ROBERT MARTELL</i> <b>Robert Martell</b>	Director	March 13, 2013
<i>/s/ KENNETH PIENTA</i> <b>Kenneth Pienta</b>	Director	March 13, 2013

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/s/ MARC RUBIN

Director

March 13, 2013

**Marc Rubin**

/s/ JAMES R. TOBIN

Director

March 13, 2013

**James R. Tobin**

**Table of Contents****EXHIBIT INDEX**

Exhibit No.	Description	Form	Incorporated by Reference		Filed with this 10-K
			SEC Filing Date	Exhibit Number	
<i>Articles of Incorporation and By-laws</i>					
3.1	Restated Certificate of Incorporation of Curis, Inc.	S-4/A (333-32446)	06/19/00	3.3	
3.2	Certificate of Designations of Curis, Inc.	S-3(333-50906)	08/10/01	3.2	
3.3	Amended and Restated By-laws of Curis, Inc.	S-1(333-50906)	11/29/00	3.2	
3.4	Amendment to Amended and Restated By-laws of Curis, Inc.	8-K	09/24/07	3.1	
<i>Instruments defining the rights of security holders, including indentures</i>					
4.1	Form of Curis Common Stock Certificate	10-K	03/01/04	4.1	
<i>Material contracts Management Contracts and Compensatory Plans</i>					
#10.1	Employment Agreement, dated as of September 18, 2007, between Curis and Daniel R. Passeri	8-K	09/24/07	10.1	
#10.2	Amendment to Employment Agreement, dated as of October 27, 2008, to the employment agreement dated September 18, 2007, by and between Curis and Daniel R. Passeri	10-Q	10/28/08	10.1	
#10.3	Amendment to Employment Agreement, dated as of December 10, 2010, to the employment agreement dated September 18, 2007, by and between Curis and Daniel R. Passeri	10-K	03/08/11	10.3	
#10.4	Letter Agreement, dated January 18, 2013, between Curis, Inc. and Daniel R. Passeri	8-K	01/18/13	10.1	
#10.5	Offer Letter, dated as December 10, 2003, between Curis and Michael P. Gray	10-K	03/01/04	10.4	
#10.6	Amendment to Offer Letter, dated as of October 31, 2006, to the offer letter dated December 10, 2003, by and between Curis and Michael P. Gray	8-K	11/02/06	10.3	
#10.7	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated December 10, 2003, by and between Curis and Michael P. Gray	10-Q	10/28/08	10.2	
#10.8	Amendment to Offer Letter, dated as of December 10, 2010, to the offer letter dated December 10, 2003, by and between Curis and Michael P. Gray	10-K	03/08/11	10.7	
#10.9	Offer Letter, dated January 11, 2001, by and between Curis and Mark W. Noel	10-K	03/02/07	10.6	

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Exhibit No.	Description	Form	Incorporated by Reference		Filed with this 10-K
			SEC Filing Date	Exhibit Number	
#10.10	Amendment to Offer Letter, dated as of October 31, 2006, to the offer letter dated January 11, 2001, by and between Curis and Mark W. Noel	8-K	11/02/06	10.4	
#10.11	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated January 11, 2001, by and between Curis and Mark W. Noel	10-Q	10/28/08	10.4	
#10.12	Amendment to Offer Letter, dated as of December 10, 2010, to the offer letter dated January 11, 2001, by and between Curis and Mark W. Noel	10-K	03/08/11	10.16	
#10.13	Employment Agreement, dated November 7, 2011, by and between Curis and Maurizio Voi	8-K	11/10/11	10.1	
#10.14	Severance Agreement, effective as of February 24, 2012, between Curis, Inc. and Changgeng Qian, Ph.D., M.D.	8-K	03/01/12	10.1	
#10.15	Consulting Agreement, dated as of February 24, 2012, between Curis, Inc. and Changgeng Qian, Ph.D., M.D.	8-K	03/01/12	10.2	
#10.16	Agreement for Service as Chairman of the Board of Directors, between Curis, Inc. and James McNab, dated as of June 1, 2005	8-K	06/07/05	10.1	
#10.17	Scientific Advisory and Consulting Agreement, between Curis, Inc. and Dr. Kenneth J. Pienta, dated as of September 13, 2006, as amended.	8-K	03/11/13	10.1	
#10.18	Form of Indemnification Agreement, between Curis, Inc. and each member of the Board of Directors	10-K	03/08/11	10.23	
#10.19	Curis 2000 Stock Incentive Plan	S-4/A (333-32446)	05/31/00	10.71	
#10.20	Curis 2000 Director Stock Option Plan	S-4/A (333-32446)	05/31/00	10.72	
#10.21	Curis 2000 Employee Stock Purchase Plan	S-4/A (333-32446)	05/31/00	10.73	
#10.22	Form of Incentive Stock Option Agreement granted to directors and named executive officers under Curis 2000 Stock Incentive Plan	10-Q	10/26/04	10.2	
#10.23	Form of Non-statutory Stock Option Agreement granted to directors and named executive officers under Curis 2000 Stock Incentive Plan	10-Q	10/26/04	10.3	
#10.24	Form of Non-statutory Stock Option Agreement granted to non-employee directors under Curis 2000 Director Stock Option Plan	10-Q	10/26/04	10.4	
#10.25	Curis 2010 Stock Incentive Plan	Def 14A	04/16/10	Exhibit A	
#10.26	Curis 2010 Employee Stock Purchase Plan	Def 14A	04/16/10	Exhibit B	

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Exhibit No.	Description	Form	Incorporated by Reference		Filed with this 10-K
			SEC Filing Date	Exhibit Number	
#10.27	Form of Incentive Stock Option Agreement granted to directors and named executive officers under Curis 2010 Stock Incentive Plan	8-K	06/04/10	10.1	
#10.28	Form of Non-Statutory Stock Option Agreement granted to directors and named executive officers under Curis 2010 Stock Incentive Plan	8-K	06/04/10	10.2	
#10.29	Form of Restricted Stock Agreement granted to directors and named executive officers under Curis 2010 Stock Incentive Plan	8-K	06/04/10	10.3	
<i>Material contracts Leases</i>					
10.30	Lease, dated September 16, 2010, between Curis, Inc. and the Trustees of Lexington Office Realty Trust relating to the premises at 4 Maguire Road, Lexington, Massachusetts	8-K	9/21/10	10.1	
<i>Material contracts Financing Agreements</i>					
10.31	Credit Agreement, dated November 27, 2012, by and between Curis, Curis Royalty LLC, a wholly-owned subsidiary of Curis and BioPharma Secured Debt Fund II Sub, S.à r.l.				X
10.32	Consent and Payment Direction Letter Agreement, dated November 20, 2012 and effective as of December 11, 2012 between Curis, Curis Royalty LLC and Genentech, Inc.				X
10.33	Purchase and Sale Agreement, dated as of December 11, 2012 between Curis and Curis Royalty				X
10.34	Escrow Agreement, dated December 11, 2012, by and between Curis, Curis Royalty LLC, a wholly-owned subsidiary of Curis, BioPharma Secured Debt Fund II Sub, S.à r.l., a Luxembourg limited liability company managed by Pharmakon Advisors and Boston Private Bank and Trust Company				X
<i>Material contracts License and Collaboration Agreements</i>					
10.35	Collaborative Research, Development and License Agreement, dated June 11, 2003, between Curis and Genentech, Inc.	10-Q	11/06/2012	10.1	
10.36	License Agreement, dated August 5, 2009, by and between the Company and Debiopharm S.A	10-Q	10/29/09	10.1	
10.37	Definitive Agreement, dated November 29, 2011, by and between Curis and The Leukemia and Lymphoma Society				X
10.38	Drug Development Partnership and License Agreement, dated as of February 24, 2012, between Curis and Guangzhou BeBetter Medicine Technology Co, LTD.	10-Q	05/10/2012	10.1	
10.39	License Agreement, dated November 27, 2012, by and between Curis and Genentech, Inc.				X



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Exhibit No.	Description	Form	Incorporated by Reference		Filed with this 10-K
			SEC Filing Date	Exhibit Number	
<b>Material contracts Miscellaneous</b>					
10.40	Placement Agent Agreement, dated January 22, 2010, by and among the Company, RBC Capital Markets Corporation and Rodman & Renshaw, LLC	8-K	1/22/10	1.1	
10.41	Form of Subscription Agreement, dated as of January 22, 2010, by and among the Company and the investors named therein	8-K	1/22/2010	10.1	
10.42	Form of Warrant, dated January 22, 2010, issued pursuant to the Subscription Agreement, dated as of January 22, 2010	8-K	1/22/2010	4.1	
10.43	At Market Issuance Sales Agreement, dated June 13, 2011, by and between the Company and McNicoll, Lewis & Vlak, LLC	8-K	06/13/11	1.1	
<b>Code of Conduct</b>					
14	Code of Business Conduct and Ethics	10-K	03/08/11	14	
<b>Additional Exhibits</b>					
21	Subsidiaries of Curis				X
23.1	Consent of PricewaterhouseCoopers LLP				X
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act/15d-14(a) of the Exchange Act				X
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act/15d-14(a) of the Exchange Act				X
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b)/15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350				X
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b)/15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350				X
+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				

# Indicates management contract or compensatory plan or arrangement.

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

+ Furnished, not filed, herewith.