CURIS INC
Form 10-K
March 13, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2013

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Commission File Number 000-30347

CURIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE	**04-3505116**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

4 Maguire Road

Lexington, Massachusetts 02421

(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	NASDAQ Global 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 x

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 x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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). x 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 ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 x

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, 2013 was approximately $182,906,000.

As of March 6, 2014, there were 85,948,078 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 21, 2014, 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, 2013 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. Our primary investment is focused on the development of our proprietary targeted cancer drug candidates, including CUDC-907, an oral, small molecule drug candidate that is designed to inhibit histone deacetylase or HDAC and phosphatidylinositol-3-kinase, or PI3K enzymes and CUDC-427, an oral, small molecule drug candidate, which is designed to promote cancer cell death by antagonizing inhibitor of apoptosis, or IAP proteins. Our collaborators F. Hoffmann-La Roche Ltd, or Roche, and Genentech Inc., or Genentech, a member of the Roche Group, are commercializing and continuing the further development of Erivedge® (vismodegib), a first-in-class orally-administered small molecule Hedgehog pathway inhibitor, and our licensee Debiopharm S.A., or Debiopharm, is conducting clinical studies of Debio 0932, a small molecule inhibitor of heat shock protein 90, or HSP90.

In January 2013, we initiated a phase 1 clinical study of CUDC-907 in patients with relapsed or refractory lymphomas or multiple myeloma. The dose-escalation phase of this study is ongoing and we expect to initiate the expansion phase in select malignancies later in 2014 after establishing the recommended dose and schedule. This program is partially supported under a collaboration with The Leukemia & Lymphoma Society, or LLS.

In 2012, we licensed from Genentech the exclusive, worldwide rights for the development and commercialization of CUDC-427. Under the terms of the license agreement, we have the sole right and responsibility for all research, development, manufacturing and commercialization activities related to CUDC-427. Genentech previously conducted a phase 1 study in patients with advanced and refractory solid tumors and lymphomas where CUDC-427 was administered at escalating once daily doses for two weeks, followed by a one week rest period in 21-day cycles until disease progression or treatment discontinuation for any other reason. In July 2013, we initiated a single-agent, phase 1 dose escalation trial of CUDC-427 in patients with advanced and refractory solid tumors and lymphomas using twice-daily dosing with no rest period in 21-day cycles. In November 2013, we received written notification from the United States Food and Drug Administration, or FDA,

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that the phase 1 study of CUDC-427 was placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until we provide the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. In February 2014, we responded to FDA s request for additional data and analysis and also submitted an amendment to the current study protocol. If the partial clinical hold is lifted by the FDA, we expect to re-initiate enrollment in the phase 1 trial and also expect to initiate additional studies with CUDC-427, including a clinical trial in combination with capecitabine in HER-2 negative breast cancer patients. Additionally, and subject to the lifting of the partial clinical hold by the FDA, CUDC-427 may be further explored in selected patients with known alterations in certain genetic markers such as MALT lymphoma and other cancer indications.

Erivedge is the first and only FDA approved medicine for the treatment of metastatic or locally advanced basal cell carcinoma, or BCC, and is being developed and commercialized by Roche and Genentech under a collaboration agreement between Curis and Genentech. In January 2012, the FDA approved 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. In May 2013, Australia s Therapeutic Goods Administration, or TGA, approved Erivedge and in July 2013, the European Commission granted conditional approval for the marketing of Erivedge in all 28 European Union member states. A conditional marketing authorization is granted to medicinal products with a positive benefit/risk assessment that satisfy an unmet medical need and whose availability results in a significant public health benefit. Erivedge s approval in the United States, Europe, Australia and several other countries and Roche s regulatory submissions in regards to Erivedge in other territories are based on positive clinical data from ERIVANCE BCC/SHH4476g, a pivotal phase 2 study of Erivedge in patients with advanced BCC. Under the provisions of the conditional approval, Roche is expected to provide additional data on Erivedge in advanced BCC from the ongoing global safety study, known as STEVIE, which is an international, single-arm, open-label multicenter trial in patients with advanced forms of BCC. An interim analysis from STEVIE confirmed a safety profile similar to that observed in previous studies of Erivedge in BCC patients. In addition, Genentech recently completed evaluation of Erivedge in a phase 2 study to treat less severe forms, or operable, BCC, and expects to present the results from this trial at the American Association of Dermatology s Annual Meeting in March 2014. Roche has also initiated a randomized, placebo controlled phase 2 study to investigate the efficacy of 12 weeks of Erivedge treatment (versus placebo) prior to surgery in previously untreated BCC patients. In October 2013 Roche also initiated a phase 1b/2 clinical trial of Erivedge in patients with relapsed/refractory acute myelogenous leukemia, or AML, and relapsed/refractory high-risk myelodysplastic syndrome, or MDS. Third-party investigators are also conducting several additional clinical trials with Erivedge.

We are also party to a license agreement with Debiopharm pursuant to which Debiopharm is developing Debio 0932. Debiopharm completed a phase 1b expansion study of Debio 0932 in patients with advanced solid tumors and expects to present data from this study at a medical conference in 2014. Debiopharm is also currently testing Debio 0932 in a phase 1/2 clinical trial (HALO study) in patients with advanced non-small cell lung cancer, or NSCLC, in combination with standard-of-care chemotherapy regimens in the front and second line settings. In October, 2013, Debiopharm also initiated a phase 1/2 study of Debio 0932 in combination with everolimus in patients with advanced metastatic renal cell carcinoma, or RCC.

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.

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

Drug candidate	Primary Disease	Collaborator/Licensee	Status
Dual HDAC and PI3K Inhibitor			
- CUDC-907	Advanced lymphomas and multiple myeloma	Internal development/LLS	Phase 1
Antagonist of IAP Proteins			
- CUDC-427	Advanced solid tumor & lymphomas including potential expansion cohort of ovarian and fallopian tube derived cancers	Internal development	Phase 1* partial clinical hold since November 5, 2013
Hedgehog Pathway Inhibitor			
- Erivedge®	Advanced BCC	Genentech (Roche)	Approved in US, EU, Australia and others; Regulatory submissions/ approvals pending in certain other territories
- Erivedge®	Operable Nodular BCC	Genentech (Roche)	Completed Phase 2
- Erivedge®	Operable BCC	Genentech (Roche)	Phase 2
- Erivedge®	Relapsed/Refractory AML and High Risk MDS	Roche	Phase 1b/2
HSP90 Inhibitor			
- Debio 0932	Advanced NSCLC	Debiopharm	Phase 1/2
- Debio 0932	Advanced RCC	Debiopharm	Phase 1/2

* A first Phase 1 clinical trial was conducted by Genentech in advance solid tumors and lymphomas prior to Curis acquisition of CUDC-427. Curis initiated a Phase 1 trial in 2013 which is currently on FDA clinical hold.

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, 2013, 2012 and 2011, milestone and royalty payments from Genentech accounted for $14,233,000, or 95%, $15,893,000, or 94%, and $14,388,000, or 97%, respectively, of our revenue, all of which was related to the development and commercialization of Erivedge.

Our Proprietary Drug Candidates

Human cancers 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 are developing 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-907. CUDC-907 is an orally bioavailable, small molecule drug candidate designed to inhibit primarily class I and IIB HDAC enzymes and PI3K alpha, delta and beta isoforms. It is known that the PI3K pathway plays an important role in cancer cell initiation, growth, proliferation, and survival, and that the PI3 kinases are frequently activated through mutations or by receptor tyrosine kinases in many cancer types. While targeting certain of the specific isoforms of PI3K alone has demonstrated clinical activity in certain cancers such as indolent non-Hodgkin s lymphoma, drug resistance often emerges in part due to the activation of other survival/ growth pathways within the cancer environment. HDAC inhibitors on the other hand, can affect a number of cell functions by regulating both histone and non-histone substrates. We believe it may be possible to address at least some of the limitations of targeting the PI3K pathway by disrupting multiple survival pathways through simultaneous inhibition of HDAC. Additionally, HDAC inhibitors such as romidepsin or Istodax™ and vorinostat or Zolinza™ are approved for the treatment of certain hematologic malignancies, including cutaneous T-cell lymphoma and/ or peripheral cutaneous t-cell lymphoma, and a number of PI3K inhibitors are in clinical

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development for various hematologic and solid tumor indications. For example, PI3K-delta subtype specific inhibitors have demonstrated clinical benefit for patients with certain types of lymphomas and PI3K-alpha specific inhibitors as well as pan-PI3K inhibitors are being studied in multiple clinical trials in patients with solid tumors. Concurrent inhibition of HDAC and PI3K has demonstrated synergistic effect in certain preclinical cancer models in hematological and other cancers. Specifically, CUDC-907 has shown potent antitumor activity in a variety of hematologic tumor models including non-Hodgkin s lymphoma and multiple myeloma.

In January 2013, we treated the first subject in a phase 1 clinical trial in patients with advanced lymphoma or multiple myeloma. The phase 1 clinical trial is designed as a standard dose escalation study in which CUDC-907 is 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, and recommended phase 2 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. In July 2013, we submitted an amendment to the protocol of the ongoing phase 1 study to include two additional dosing schedules, wherein oral CUDC-907 is administered either two times per week or three times per week. Additionally, exploratory biomarkers will be assessed for the activity of CUDC-907.

We presented interim data from this study at the Annual Meeting of the American Society of Hematology on 13 safety evaluable patients who received regimens at doses of 30 mg (n=7) or 60 mg (n=3) once daily, or 60 mg two times per week (n=3). Dose limiting toxicities, or DLTs of Grade 3 diarrhea and Grade 4 hyperglycemia were both reported in one patient at the 60 mg once daily dose. In addition to these events, one other treatment-related serious adverse event of Grade 3 epistaxis (30 mg once daily, n=1), was also reported with the daily schedule. To date, the most frequent Grade 3 or 4 adverse events reported in two or more patients include thrombocytopenia, diarrhea and neutropenia. These toxicities limited the ability to dose escalate beyond 60 mg using the once daily dosing schedule. Data presented suggest that the intermittent dosing is better tolerated than once daily dosing and dose escalation continues in both the two times per week and three times per week dose groups.

Out of the 13 safety evaluable patients, 11 were evaluable for response assessment per protocol. One patient with mixed follicular lymphoma/diffuse large B cell lymphoma achieved a partial response, or PR, consisting of 70% reduction in a single target lesion observed at the 30 mg once daily dose level. Seven other patients have met criteria for stable disease, including four with stable disease lasting at least four cycles of treatment. One of the patients with stable disease is a multiple myeloma patient and has remained on study since initial treatment in January 2013.

Preliminary pharmacokinetic analysis shows low CUDC-907 plasma levels as compared to its metabolite species, M1 (minimal PI3K inhibitory activity and no HDAC inhibitory activity) and M2 (significant PI3K inhibitory activity and no HDAC activity). This is consistent with animal studies that demonstrated higher levels of CUDC-907 in tissues as compared to plasma. Additional pharmacokinetic and pharmacodynamic analyses are ongoing. We expect to complete the dose-escalation phase in the middle of 2014 and initiate enrollment in the expansion cohort(s) in patients with select malignancies in the second half of 2014. In addition to our ongoing phase 1 clinical study in advanced lymphomas and multiple myeloma patients, we are conducting preclinical studies with CUDC-907 in solid tumor models and currently anticipate that we will initiate additional studies using CUDC-907 monotherapy or in combination with other anti-cancer agents in patients with solid tumors later in 2014.

We are party to an agreement with The Leukemia & Lymphoma Society, or LLS, pursuant to which LLS will, upon achievement of specified milestones, provide up to $4,000,000 in payments to support our ongoing

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development of CUDC-907. Through December 31, 2013, we have earned an aggregate of $1,650,000 in milestone payments under the terms of the agreement with LLS. We will be obligated to make contingent payments in the future, including potential royalty payments, upon our successful entry into a partnering agreement for CUDC-907 or upon the achievement of regulatory and commercial objectives, with such future payments capped at 2.5 times the 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 the agreement earlier terminates or expires 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.

CUDC-427. In 2012, we licensed from Genentech the exclusive, worldwide rights for the development and commercialization of CUDC-427, an oral, small molecule Smac mimetic 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.

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. 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 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.

Prior to our licensing agreement, Genentech had completed enrollment in a phase 1 clinical trial of CUDC-427 (previously GDC-0917), in which 42 patients with refractory solid tumors or lymphoma received daily oral doses of CUDC-427 for two weeks, followed by a one week rest period in 21-day cycles until disease progression or treatment discontinuation for any other reason. In this study, patients were enrolled across 11 dose cohorts and received CUDC-427 monotherapy at doses ranging from 5 mg to 600 mg daily. Unconfirmed complete responses were reported in 2 patients, including one patient with ovarian cancer and another with mucosa-associated lymphoid tissue, or MALT, lymphoma. Additionally, one patient experienced a mixed response and four patients (one patient each with breast cancer, sarcoma, small cell lung cancer and Kaposi s sarcoma) had stable disease for at least three months, including one patient who continued to receive CUDC-427 for more than 10 months. The maximum tolerated dose of CUDC-427 was not determined in this study, although plasma concentrations in the order of pre-clinically predicted ED90 were reached. ED90 refers to the dose that leads to 90% of the maximal response. Three deaths were reported on that study, none of which was considered related to the study drug: two patients died due to progression of breast cancer and one patient died due to pneumonia. Adverse events, or AEs, that resulted in treatment discontinuation were Grade 3 fatigue (one patient), Grade 2 QTc prolongation (one patient), Grade 2 drug hypersensitivity (one patient), Grade 2 pneumonitis (one patient), and Grade 3 pruritus/Grade 2 rash (one patient). Other treatment related AEs that were equal to or greater than Grade 3 in severity in more than one patient were elevated levels of liver enzymes (two patients at 450 and 600 mg doses). Biomarker analyses of tumor samples (obtained from two patients) and peripheral blood cells (obtained from all patients) showed changes that were consistent with CUDC-427 s mechanism of action.

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During the third quarter of 2013, the first patient was treated in our open-label, multicenter phase 1 study of CUDC-427 in patients with relapsed/refractory solid tumors or lymphoma. The study is designed to determine the maximum tolerated dose and the recommended phase 2 dose of CUDC-427 administered as a single agent using a continuous, twice-daily treatment schedule in 21-day cycles. Upon determination of the recommended dose, the trial is designed to enroll up to an additional 12 patients in the expansion cohort of a particular cancer type, for example, in ovarian and fallopian tube cancers. The secondary objectives of the study are to assess CUDC-427 s safety and tolerability, pharmacokinetics, exploratory biomarkers of activity and preliminary anti-cancer activity. In November 2013, the FDA placed this phase 1 study on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing.

This event occurred in one patient with breast cancer metastatic to the liver, lungs, bone and ovaries who developed evidence of liver injury related to liver function, including increases in serum levels of liver enzymes (ie, ALT and AST) and total bilirubin. Unlike prior clinical experience with CUDC-427, this patient s liver enzymes did not recover in response to stopping CUDC-427 treatment and the patient died of liver failure approximately one month following the discontinuation of CUDC-427 dosing. While elevations in liver enzyme levels have previously occurred in patients receiving CUDC-427, no other patients in this or the prior phase 1 CUDC-427 trial have experienced a serious adverse event of this nature.

A clinical hold, including a partial clinical hold, involves the FDA (1) requiring additional information and/or data, (2) reviewing the additional information and/or data, and (3) after the review, informing the sponsor whether or not they can proceed. A partial clinical hold is defined as a delay or suspension of only part of the clinical work requested under the IND (e.g., a specific protocol or part of a protocol is not allowed to proceed; however, other protocols or parts of the protocol are allowed to proceed under the IND). Under the partial clinical hold described above, new patients may not be enrolled in the study until Curis provides the FDA with requested additional data and analysis of patients treated with CUDC-427. Additionally, a proposed protocol amendment must be submitted to and accepted by the FDA. No patients are currently being treated with CUDC-427 as all other patients previously enrolled on this study have discontinued dosing due to disease progression or patient or physician discretion during the ordinary course of the study.

In February 2014, we responded to the FDA s request for additional data and analysis and also submitted an amendment to the current study protocol. If the partial clinical hold is lifted by the FDA, we expect to re-initiate enrollment in the phase 1 trial and also expect to initiate additional studies with CUDC-427.

Both Curis and Genentech may terminate the 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 license agreement prior to expiration for any reason upon 90 days prior written notice to Genentech. Upon any termination of the license agreement, the license granted to us will terminate and revert to Genentech. If Genentech terminates the license agreement for an uncured material breach by us, or if we terminate 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 we may, under specified circumstances, be obligated to supply products to Genentech for a limited period after termination.

CUDC-101. In April 2013, we determined that we would discontinue enrolling patients in our phase 1 expansion trial of the intravenous formulation of CUDC-101, a drug candidate that was designed to target HDAC enzymes and epidermal growth factor receptor, and that the future development of CUDC-101 would be dependent on our ability to successfully develop an oral formulation of CUDC-101. Our efforts to develop an effective oral formulation with improved bioavailability have not resulted in significant improvements when compared to the intravenous formulation of CUDC-101. As a result, while we continue to explore possible collaboration or other mechanisms to further advance this molecule, at this time we no longer plan to make material investments in this program.

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Our Collaborations

Genentech

Erivedge. 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 an orally bioavailable small molecule which is designed to selectively inhibit the Hedgehog signaling pathway by targeting a protein called Smoothened. Genetic mutations that lead to unregulated activation of Hedgehog signaling are found in BCC and medulloblastomas. Aberrant signaling in the Hedgehog pathway is implicated in over 90% of BCC cases. Many other cancers have abnormal Hedgehog signaling that is not linked to Hedgehog pathway mutations.

Erivedge is FDA-approved for adults with advanced forms of BCC and is being developed in various cancer indications under a collaboration agreement with Genentech. Genentech and Roche are responsible for the clinical development and commercialization of Erivedge and it is currently marketed and sold in the U.S. Erivedge is also approved for use in the European Union, Australia, Canada, Israel, Mexico and several other countries and Roche has begun selling Erivedge in several territories outside of the U.S. It is also under regulatory review in multiple other territories worldwide.

In 2013, Genentech and Roche completed a phase 2 clinical trial of Erivedge in operable BCC. Genentech and Roche expect to present results from this study at the American Academy of Dermatology s Annual Meeting in March 2014. In October, 2013, Roche initiated a phase 1b/2 clinical trial of Erivedge in patients with relapsed/refractory AML and relapsed/refractory high-risk MDS. In addition, Erivedge is currently being tested in multiple clinical trials for the 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 FDA as the first and only FDA-approved medicine for adults with advanced forms of BCC. 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 or when there is no issued intellectual property covering Erivedge in a territory in which sales are recorded.

In November 2012, in connection with a $30,000,000 loan made by BioPharma Secured Debt Fund II Sub, S.à r.l., or BioPharma-II, a Luxembourg limited liability company managed by Pharmakon Advisors to our subsidiary Curis Royalty, LLC, or 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, which bears interest at an annual rate of 12.25% 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

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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 $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 2016, there are no caps to the amounts Curis Royalty will be required to make to BioPharma-II. 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 until it is repaid in full. As of December 31, 2013, the balance of principal plus accrued interest on the loan to Curis Royalty, gross of issuance costs, was $31,013,000. We currently estimate that the loan will be fully repaid in the first half of 2017. However, the actual repayment period could vary materially from our estimate to the extent that royalty payments we receive are lower than our current estimates, which could arise due to factors beyond our control, such as due to competitive factors, decreased market acceptance, a failure by Genentech and/or Roche to obtain required regulatory approvals, and other factors described under Part I, Item 1A Risk Factors.

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

In May 2013, Australia s TGA approved Erivedge. In July 2013, the European Commission granted conditional approval for the marketing of Erivedge in all 28 European Union member states. This conditional approval makes Erivedge the first licensed treatment in Europe for advanced BCC. A conditional marketing authorization is granted to medicinal products with a positive benefit/risk assessment that satisfy an unmet medical need and whose availability results in a significant public health benefit. Under the provisions of the conditional approval, Roche is expected to provide additional data on Erivedge in advanced BCC from the ongoing global safety study, known as STEVIE. An interim analysis from STEVIE confirmed a similar safety profile to that observed in the pivotal ERIVANCE BCC study.

Operable BCC. Genentech also conducted a separate phase 2 clinical trial of Erivedge in patients with operable nodular BCC, which is a less severe form of the disease. This phase 2 trial is the first study in patients with operable BCC lesions and aims to assess whether Erivedge can achieve complete clearance of tumor as measured by histological examination. This is an important first step in determining the efficacy of Erivedge in less severe forms of BCC that are generally effectively treated surgically. This trial was designed to test different durations of treatment with Erivedge in patients with operable nodular BCC. The study was conducted in the U.S. and was designed as an open label trial enrolling approximately 75 patients in three cohorts. Patients in the first and second cohorts received a 150 mg daily oral dose of Erivedge for 12 weeks. Patients in the third cohort received daily doses of Erivedge using the following administration regimen: eight weeks 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).

The first cohort evaluated the safety and efficacy of 12 weeks of 150 mg daily dosing of Erivedge in 24 patients with newly diagnosed operable nodular BCC. Patients then underwent Mohs surgery with independent

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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 lower 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 spasms. No serious adverse events were reported. Eight patients (33%) discontinued the study, including two (8%) due to adverse events. This study is now complete, and Genentech and Roche expect to present results of this trial at the American Academy of Dermatology Annual Meeting in March 2014.

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 trials under collaborative agreements between Genentech and either third-party investigators or the NCI.

In October 2013, Roche initiated a phase 1b/2 clinical trial in patients with relapsed/refractory AML and relapsed/refractory high-risk MDS. In contrast to BCC, these two clinical conditions are driven by mechanisms that are not linked to mutations in the Hedgehog pathway. This phase 1b/2 study is designed to investigate the safety and efficacy of Erivedge in these patients. According to Roche, the open-label, non-randomized study is expected to enroll approximately 60 patients into two cohorts. Patients in Cohort 1 will receive 150 milligrams of Erivedge alone once daily, and patients in Cohort 2 will receive the same dose of Erivedge once daily in combination with the standard dose of cytarabine administered for 10 days. The primary endpoint of the trial is the overall response rate after eight weeks of treatment. The secondary endpoints include overall response rate at any time during treatment, duration of response, overall survival, and safety and pharmacokinetics of the study drug(s).

Genentech Collaboration Agreement. Under the terms of our collaboration agreement with Genentech, we granted Genentech an exclusive, global, royalty-bearing license, with the right to sublicense, to make, use, sell and import molecules capable of inhibiting the Hedgehog pathway (including small molecules, proteins and antibodies) for human therapeutic applications, including cancer therapy. Genentech subsequently granted a sublicense to Roche for non-U.S. rights to Erivedge. 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 $56,000,000 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 owed by Curis Royalty to BioPharma-II, up to the quarterly caps for 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 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.

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Debiopharm

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, Debio 0932 achieved tumor regressions in acute myelogenous leukemia, breast, NSCLC, glioblastoma, gastric and colon cancer models.

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 1 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 1 study. 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. 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 NSCLC 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 1b expansion portion of the monotherapy study, which has now been completed and enrolled approximately 30 patients with advanced solid tumors, including NSCLC. Debiopharm has stated that it expects to report data from this study at a medical conference in 2014.

In August 2012, Debiopharm initiated the HALO study. This study is a phase 1/2 clinical trial testing the safety and efficacy of Debio 0932 in combination with standard of care first- or second-line chemotherapy agents in patients with advanced, stage 3b or 4 NSCLC that is characterized as wild-type EGFR. The phase 1 portion of this trial is designed to determine the recommended phase 2 dose of Debio 0932 when given in combination with cisplatin/pemetrexed or cisplatin/gemcitabine in treatment-naive patients (i.e., first-line), or with docetaxel in previously treated patients (i.e., second-line). Assuming the phase 1 trial is completed successfully and the recommended phase 2 dose(s) of Debio 0932 is identified, Debiopharm expects to conduct a randomized, double-blind, placebo-controlled phase 2 portion of this study where eligible patients will be randomized to receive chemotherapy in combination with either placebo or Debio 0932.

In October 2013, Debiopharm initiated an open-label, multicenter phase 1 dose-finding study of Debio 0932, in combination with everolimus, an inhibitor of mammalian target of rapamycin, or mTOR, in patients with advanced or metastatic RCC who have been previously treated with a VEGF-directed tyrosine kinase inhibitor. This dose escalation study is designed to determine the safety and maximum tolerated dose of Debio 0932 in combination with everolimus, in previously treated patients with advanced/metastatic RCC. The pharmacokinetic profiles and any potential drug-drug interactions between the two agents will also be assessed. The trial also includes an expansion cohort of 25 patients with metastatic clear cell RCC.

Pursuant to the terms of our agreement with Debiopharm, in addition of funds received to date, we are eligible to receive up to an additional $77,000,000 if specified clinical development and regulatory approval objectives are met. We will receive a milestone payment if and when Debiopharm treats its fifth patient in a phase 2 clinical trial. We currently anticipate that phase 2 testing could commence in 2014 for the NSCLC study. We are also eligible to receive royalties if any products under the license agreement are successfully

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developed and commercialized. Subject to specified exceptions, we are entitled to a high single digit to low double digit royalty for net sales of Debio 0932 that are made directly by Debiopharm, escalating within this range with increasing product sales. 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 10th 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 using 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.

Website Access to Reports

We maintain a website with the address 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, 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.

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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 97 issued or allowed patents expiring on various dates between 2014 and 2031 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 73 issued U.S. patents or allowed U.S. applications expiring on various dates between 2014 and 2031, 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 covering the IAP inhibitor CUDC-427, which includes two issued U.S. patents that expire in 2025 as well as an allowed application. The portfolio consists of a broad filing which cover a genus of compounds which embrace CUDC-427 and their methods of use thereof, as well as a narrow filing 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 18 issued or allowed U.S. patents which expire on various dates between 2027 and 2030, 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.

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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, 2013, our research and development group consisted of 19 employees, including oncologists, molecular biologists, cell biologists, chemists, pharmacologists and other clinical or scientific disciplines.

The amounts spent on company-sponsored research and development activities for the years ended December 31, 2013, 2012 and 2011 were $12,927,000, $15,492,000 and $13,693,000, respectively. We had no collaborator-sponsored research and development expense for the years ended December 31, 2013, 2012 and 2011.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or DOJ or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA s good laboratory practice, or GLP, regulations;

- submission to the FDA of an IND, which must take effect before human clinical trials may begin;

- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;

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performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;

preparation and submission to the FDA of a new drug application, or NDA;

review of the product by an FDA advisory committee, where appropriate or if applicable;

satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product s identity, strength, quality and purity;

payment of user fees and securing FDA approval of the NDA; and

compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

In addition, an IRB representing 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 and reapprove the study at least annually. 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. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease (e.g. cancer) or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

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Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of a new drug application, or NDA, requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently exceeding $2.1 million, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently exceeding $104,000 per product and $554,000 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA s receipt of the submission to determine whether the application is 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 in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for priority review products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as Active Pharmaceutical Ingredients), finished drug product manufacturing, and control testing laboratories. 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. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA also may require submission of a REMS plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

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The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product s NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA s time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Improvement Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as breakthrough therapies. A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA s goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that

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can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor s agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug s clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA s Decision on an NDA

On the basis of the FDA s evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

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Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug

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product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product will be entitled to orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of a NDA, plus the time between the submission date of a NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product s approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure.

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The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state s assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Data and Market Exclusivity in the European Union

In the European Union, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator s data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator s data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the drug if such company can complete a full MAA with a complete database of pharmaceutical test, pre-clinical tests and clinical trials and obtain marketing approval of its product.

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.

There are several companies developing drug candidates that target the same molecular targets and signaling pathways, and in some cases the same cancer indications, that are being pursued by us and our collaborators. We believe our primary competitors by molecular target as are as follows:

CUDC-907: We are not aware of other molecules in clinical testing that are designed as one chemical entity to target both PI3K and HDAC. However, there are commercially-available drugs that individually target HDAC. For example, commercially available HDAC inhibitors include Zolinza™ (vorinostat), which is produced by Merck & Company, and Istodax™ (romidepsin), which is produced by Celgene Corporation. In addition, there are several companies testing novel HDAC inhibitors in clinical trials, including among others, Novartis International AG (panobinostat), Mirati Therapeutics (mocetinostat), Syndax Pharmacuticals, Inc. (entinostat), MEI Pharma, Inc. (pracinostat), 4SC AG (resminostat and 4SC-202), Acetylon Pharmaceuticals, Inc. (ricolinostat), Italfarmaco S.p.A. (givinostat), Spectrum Pharmaceuticals, Inc. (belinostat), EnVivo Pharmaceuticals (ENP-0334) and Celleron Therapeutics (CXD101). There are multiple companies testing various PI3K inhibitors- both isoform specific and pan-PI3K inhibitors, which are in various stages of clinical development. Some of these companies include Gilead Sciences, Inc. (idelalisib, GS-9020), Novartis (BKM120/ buparlisib, BYL719), Bayer AG (copanlisib/ BAY 80-6946), Genentech/ Roche (GDC-0941, GDC-0032), Infinity Pharmaceuticals Inc (IPI-145), Wilex AG (WX-037), Oncothyreon Inc. (PX-866), Takeda Pharmaceutical Company Limited (MLN1117), GlaxoSmithKline plc (GSK2636771), Pfizer Inc. (PF-05212384, PF-04691502), Sanofi (SAR245409), TG Therapeutics, Inc. (TGR-1202), Incyte Corporation (INCB040093), Zenyaku Kogyo Co., Ltd (ZSTK474) and Verastem, Inc. (VS-5584).

CUDC-427: In addition of Curis, we are aware of several other companies developing antagonists of IAP proteins including, among others, Debiopharm SA (Debio 1143), Novartis AG (LCL161) and TetraLogic Pharmaceuticals, Inc. (birinapant).

Erivedge. 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 advanced Hedgehog pathway inhibitors into clinical development: Eli Lilly and Company (LY2940680), Exelixis, Inc./Bristol-Myers Squibb Company (BMS-833923 or XL139)); Pfizer Inc. (PF-04449913) and Novartis (LDE225), which recently announced that its Hedgehog inhibitor met the primary endpoint in a pivotal trial in patients with advanced basal cell carcinoma. Other Hedgehog pathway inhibitors are in earlier stages of clinical development. Under the terms of our collaboration agreement with Genentech, our royalty would be reduced in any country where another drug that binds to the same molecular target receives regulatory approval for the same indication as Erivedge and is subsequently commercialized in that country.

Debio-0932: Several companies are investigating HSP90 inhibitors in clinical testing, including, among others, Astex Therapeutics Ltd. (AT13387), Daiichi Sankyo Inc. (DS-2248), Esanex, Inc. (SNX-5422), Kyowa Hakko Kirin Co, Ltd. (KW-2478), Novartis International AG (AUY922), Samus Therapeutics, Inc. (PU-H71) and Synta Pharmaceuticals Corp (ganetespib).

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 that we are developing would also compete with those being developed by academic and research institutions, government agencies and other

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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(s) 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.

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, 2013, we had 33 full-time employees, of whom 7 hold a Ph.D. or other advanced scientific or medical degree. Of our employees, 19 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.

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Executive Officers of the Registrant

Our executive officers are as follows:

Name	Age	Position
Daniel R. Passeri, MSc., J.D.	53	Chief Executive Officer
Ali Fattaey, Ph.D	49	President and Chief Operating Officer
Michael P. Gray	43	Chief Financial Officer
Jaye Viner, M.D, MPH	57	Chief Medical Officer and Executive Vice President

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.

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.

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Name	Age	Position
Jaye Viner, M.D, MPH		Dr. Viner has served as our Chief Medical Officer since August 2013. From April 2009 until April 2012, Dr. Viner served as a Medical Director at Millennium: The Takeda Oncology Company, a biotechnology company. From April 2012 until August 2013, Dr. Viner served as an Associate Director, Clinical Development Oncology at MedImmune, LLC. (AstraZeneca). From 1995 until March 2009, Dr. Viner held senior leadership positions at the National Cancer Institute and the National Institutes of Health, including Deputy and Acting Director of the Office of Centers, Training and Resources, and Chief of the Gastrointestinal and Other Cancers Research Group in the Division of Cancer Prevention. Dr. Viner received her medical degree from the University of Virginia School of Medicine and her master s degree in Public Health from Johns Hopkins University Bloomberg School of Public Health.

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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, 2013, we had an accumulated deficit of approximately $760,827,000. We have incurred net losses of $12,322,000, $16,417,000 and $9,859,000 for the years ended December 31, 2013, 2012 and 2011, respectively. Other than Erivedge, which was developed and is being commercialized by our collaborators Roche and Genentech, we have not successfully commercialized any products to date, either alone or in collaboration with others.

We have historically derived a substantial portion of our operating cash flow from the research funding, milestone payments and royalty revenues under collaboration agreements with third parties. 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.

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. Our wholly-owned subsidiary Curis Royalty, received a $30,000,000 loan pursuant to a credit agreement entered into by and among Curis, Curis Royalty and BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to certain future royalty and royalty-related payments on commercial sales of Erivedge by Genentech. The loan and accrued interest 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. Curis Royalty will be entitled to receive and distribute to Curis only those royalty amounts, if any, in excess of the amounts it is required to remit each quarter to BioPharma-II. 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 remit such royalties to BioPharma-II in repayment of the loan.

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

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for substantial working capital to support our research and development activities for CUDC-427, if the FDA s partial clinical hold is lifted, CUDC-907, and other drug candidates that we may seek to develop in the future and to fund our general and administrative costs and expenses.

We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at December 31, 2013 should enable us to maintain current and planned operations into 2016. 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;
- the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates;
- the costs of commercialization activities for any of our product candidates that receive marketing approval, to the extent such costs are not the responsibility of one of our collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities
- unplanned costs to prepare, file, prosecute, 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.

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

Identifying potential drug candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our drug candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drug candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

We may seek additional funding through public or private financings of debt or equity. For example, in July 2013 we entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, pursuant to which, from time to time, we may offer and sell up to $30,000,000 of common stock registered pursuant to our universal shelf registration statement through Cowen in one or more at the market or other specified offerings, from which we have received gross proceeds of approximately $16,900,000 as of December 31, 2013. 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 of our internal development pipeline, additional funding may not be available to us on acceptable terms, if at all, and we may not be able to sell shares under the arrangement with Cowen at favorable prices, if at all. In addition, the terms of any potential financing may be dilutive or otherwise adversely affect other rights of our stockholders. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all.

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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.

In December 2012, our wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan pursuant to a credit agreement with BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that we receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to Curis.

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

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

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

- the status of, and level of expenses incurred in connection with, our preclinical and clinical development programs, including development costs relating to CUDC-427, if the FDA s partial clinical hold is lifted, and CUDC-907;
- any intellectual property infringement lawsuit or other litigation in which we may become involved;
- the implementation of restructuring and cost-savings strategies;
- the occurrence of an event of default under the credit agreement by and among Curis, Curis Royalty and BioPharma II;
- any changes in the fair value of our warrant liability;
- 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, 2013, we had $68,906,000 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, 2013, no assurance can be given that a 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 in recent years.

RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

We are reliant on Genentech and/or Roche 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. Erivedge has also been approved in a number of foreign countries. Genentech and/or Roche have filed regulatory submissions in additional territories seeking approval to commercialize Erivedge for this same indication. Genentech and Roche are also conducting a phase 2 clinical trial of Erivedge in

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nodular BCC, a phase 1b/2 trial in relapsed/ refractory AML and MDS, and Erivedge is currently being tested in other cancers under collaborative agreements between Genentech and either third-party investigators or the NCI. Our levels of revenue in each period and our near-term prospects substantially depend upon Genentech s ability to successfully develop and commercialize Erivedge in one or more additional indications and to demonstrate its safety and efficacy, as well as its superiority over existing therapies and standards of care. The development and commercialization of Erivedge could be unsuccessful if:

- Erivedge for the treatment of advanced BCC is no longer accepted as safe, efficacious, cost-effective, and preferable to current therapies in the medical community and by third-party payors;
- Genentech and/or Roche fails to continue to apply the necessary financial resources and expertise to manufacturing, marketing and selling Erivedge for advanced BCC and to regulatory approvals for this indication outside of the U.S.;
- Genentech and/or Roche do not continue to develop and implement effective marketing, sales and distribution strategies and operations, for development and commercialization of Erivedge for advanced BCC;
- Genentech and/or Roche do not continue to develop, validate and maintain a commercially viable manufacturing process for Erivedge that is compliant with current good manufacturing practices;
- Genentech and/or Roche do not successfully obtain third party reimbursement and generate commercial demand that results in sales of Erivedge for advanced BCC in any geographic areas where requisite approvals have been, or may be, obtained;
- we 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;
- competing products are approved for the same indications as Erivedge;
- new safety risks are identified; 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 retain royalty revenue under our collaboration agreement with Genentech to the extent that 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 of our wholly-owned subsidiary, Curis Royalty, to remit such royalties to BioPharma-II.

The FDA has placed a partial clinical hold on CUDC-427, one of our lead compounds under development. Our business may be adversely affected if the partial clinical hold cannot be resolved or if such regulatory concerns lead to more burdensome preclinical or clinical studies that cause significant delays in developing our drug candidates.

In November 2012, we licensed from Genentech the exclusive, worldwide rights for the manufacture, development and commercialization of CUDC-427. On November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until we provide the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. In February 2014, we responded to the FDA s request for additional data and analysis and also submitted an amendment to the current study protocol.

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We cannot assure you that the FDA will lift the partial clinical hold and allow us to pursue further development of CUDC-427. If the FDA fails to lift the partial clinical hold, our development timelines and our business would be adversely affected and our stock price may decline. Further, even if the FDA lifts the partial clinical hold, or if the FDA or other regulatory agencies continue to express safety concerns after the hold is lifted, future preclinical or clinical studies involving CUDC-427 may be more burdensome or include additional preclinical or clinical endpoints that are difficult to meet. In such instances, our progress in the development of CUDC-427 may be significantly slowed and the associated costs may be significantly increased, adversely affecting our business.

The therapeutic efficacy of targeted drug candidates being developed by us and our collaborators is unproven in humans, and we may not be able to successfully develop and commercialize drug candidates pursuant to these programs.

Our targeted drug candidates 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 their successful development and commercialization, which is subject to many potential risks. For example, our drug candidates may not prove to be effective inhibitors of the 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. These drug candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. For example, on November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 had been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. If the FDA determines that it will not lift the partial clinical hold on CUDC-427, or if any of our other drug candidates are associated with significant side effects or have characteristics that are unexpected, we may need to delay or abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. 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 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

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addition, we entered into a license agreement with Debiopharm pursuant to which Debiopharm is developing Debio 0932, our Hsp90 inhibitor. 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 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.

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.

Our collaborators may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or change of control. Any such transaction could divert the attention of our collaborative partner s management and adversely affect its ability to retain and motivate key personnel who are important to the continued development of the programs under such collaboration. In addition, an acquirer could determine to reprioritize our collaborator s development programs such that our collaborator ceases to diligently pursue the development of our programs, and/or terminates 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.

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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.

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.

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 1 or phase 2 clinical testing. We do not currently have the resources or capacity to advance these programs into later stage clinical development (i.e., phase 3) or commercialization on our own. 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 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. We are also restricted under the terms of certain of our existing collaboration agreements from entering into collaborations regarding or otherwise developing product candidates that are similar to the product candidates that are subject to those agreements, such as developing product candidates that inhibit the same molecular target. In addition, collaboration agreements that we enter into in the future may contain further restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us and such collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner or at all.

Moreover, if we fail to establish and maintain additional 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.

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

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

Development, including preclinical and clinical testing, is a long, expensive and uncertain process. Preclinical testing and clinical trials of our drug candidates may not be successful. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face similar setbacks. We and our collaborators could experience delays or failures in preclinical testing or clinical trials of any of our drug candidates for a number of reasons including, for example:

- preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results;
- we or any collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or terminate testing for a particular drug candidate;
- the results from preclinical studies and early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;
- preclinical and clinical data are often susceptible to varying interpretations and analyses and even if we, or our collaborators, believe that the results of clinical trials for our product candidates to be successful, regulatory authorities may disagree with our interpretations and analyses.
- we may encounter difficulties or delays in manufacturing sufficient quantities of the drug candidate used in any preclinical study or clinical trial;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the timing and completion of clinical trials of our drug candidates depend on, among other factors, the number of patients required to be enrolled in the clinical trials and the rate at which those patients are enrolled, and any increase in the required number of patients, decrease in recruitment rates or difficulties retaining study participants may result in increased costs, program delays or program termination;
- our products under development may not be effective in treating cancer or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use;

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

institutional review boards, regulators, including the FDA or its foreign equivalents, or any collaborators may hold, suspend or terminate our clinical research or the clinical trials of our drug candidates for various reasons, including failure to achieve established success criteria, noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks. For example, on November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 had been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing; and

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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 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, including with respect to CUDC-427 if the FDA lifts its partial clinical hold, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

be delayed in obtaining marketing approval for our drug candidates;

not obtain marketing approval at all;

obtain approval for indications that are not as broad as intended or with labeling that highlights undesirable safety risks;

have the product removed from the market after obtaining marketing approval;

be subject to additional post-marketing testing requirements;

be subject to restrictions on how the product is distributed or used; or

be unable to obtain reimbursement for use of the product.

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

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

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

the size and nature of the patient population;

the severity of the disease under investigation;

the proximity of patients to clinical sites;

the eligibility criteria and design for the trial; and

clinicians and patients perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating

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

Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause the value of our stock price to decline, which could 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, and/or the reporting of adverse events by companies with competing drug candidates, could result in significant delays or may require us to abandon one or more clinical trials altogether.

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

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

If we 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 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. For example, on November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. We cannot guarantee when or if the FDA will lift the partial clinical hold and allow us to pursue further development of CUDC-427. 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.

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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.

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

Even if we or any collaborators obtain regulatory approval of a drug candidate, such product, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping.

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit

recall of products;

fines, restitution or disgorgement of profits or revenue;

suspension or withdrawal of regulatory approvals;

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

- the federal Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians, and teaching hospitals with data collection beginning on August 1, 2013, requirements for manufacturers to submit reports to CMS by March 31, 2014 and the 90th day of each subsequent calendar year, and disclosure of such information to be made by CMS on a publicly available website beginning in September 2014; and

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

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Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

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

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

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

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

- the prevalence and severity of any side effects;
- efficacy and potential advantages compared to alternative treatments;
- the price we charge for our drugs;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to successfully develop companion diagnostics that effectively identify patient populations likely to benefit from treatment with our therapeutic products;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

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

opportunities.

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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. For example, on November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. We cannot guarantee when or if the FDA will lift the partial clinical hold and allow us to pursue further development of CUDC-427;

- 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; and Millennium: The Takeda Oncology Company. Novartis recently announced that its Hedgehog inhibitor met the primary endpoint in a pivotal trial in patients with advanced basal cell carcinoma. Under the terms of our collaboration agreement with Genentech, our royalty would be reduced in any country where another drug that binds to the same molecular target receives regulatory approval for the same indication as Erivedge and is subsequently commercialized in that country.

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, while we are not aware of other molecules in clinical testing that are designed as one chemical entity to target both PI3K and HDAC, there are commercially-available drugs that individually target HDAC and there are

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

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

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

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

Product liability claims are inherent in the process of researching, developing and commercializing human health care products and could expose us to significant liabilities and prevent or interfere with the development or commercialization of our drug candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Regardless of their merit or eventual outcome, product liability claims would require us to spend significant time, money and other resources to defend such claims, could result in

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

Although we currently have product liability insurance for our clinical trials, this insurance is subject to deductibles and coverage limitations and may not be adequate in scope to protect us in the event of a successful product liability claim. Product liability insurance is expensive and may be difficult to retain. As such, it is possible that we will not be able to retain product liability insurance on acceptable terms, if at all, or that our product liability insurance coverage will prove to be inadequate to protect us from all potential claims.

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

We depend upon our senior management team. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of product development and other

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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.

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

We may seek to expand our operations, including without limitation through internal growth and/or the acquisition of businesses and technologies that we believe are a strategic complement to our business model. We may not be able to identify suitable acquisition candidates or expansion strategies and successfully complete such acquisitions or successfully execute any such other expansion strategies. We may never realize the anticipated benefits of any efforts to expand our business. Furthermore, the expansion of our business, either through internal growth or through acquisitions, poses significant risks to our existing operations, financial condition and operating results, including:

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

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

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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 by contract research organizations 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, we cannot predict the effect of future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. Our business could be materially harmed by any changes in the political, legal or economic climate in China or 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 set forth in our Annual Report.

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;

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protect trade secrets from disclosure to third-party competitors;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

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

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

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

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties and are reliant on our licensors. For example, we do not control the prosecution of certain patent rights licensed to us under our IAP agreement with Genentech. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business.

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

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

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

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

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

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.

We have historically conducted synthetic chemistry work through a contract research agreement with a medicinal chemistry provider in China. We seek to protect our intellectual property rights under this arrangement through, among other things, non-disclosure and assignment of invention covenants. Enforcement of intellectual property rights and confidentiality protections in China may not be as effective as in the U.S. or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we might need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation 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.

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

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

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

We are party to agreements that provide for licenses to us of intellectual property or sharing of rights to intellectual property that is important to our business, and we may enter into additional agreements in the future that provide licenses to us of valuable technology. These licenses 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

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effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our and our collaborators control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us and our collaborators.

Any contract manufacturers with whom we or our collaborators enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current good manufacturing practices and other governmental regulations and corresponding foreign standards. Any failure by 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 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 commercializing Erivedge. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these

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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.

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 the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of any product candidate that we develop, restrict or regulate post-approval activities and affect our ability to profitably sell profitably or commercialize any product candidate for which we obtain marketing approval or that we may in-license. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product.

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

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

an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer s outpatient drugs to be covered under Medicare Part D;

extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level beginning in 2014, thereby potentially increasing a manufacturer s Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

the new requirements under the federal Open Payments program and its implementing regulations;

a new requirement to annually report product samples that manufacturers and distributors provide to physicians; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went

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into effect in April 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, or in-licensed products, if any, may be.

RISKS 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, 2014. 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 and any subsequent restatement of such results;
- the amount and timing of any royalty revenue we receive from Genentech related to Erivedge;
- actual or anticipated changes to our research and development plans;
- deviations in our operating results from the estimates of securities analysts;
- entering into new collaboration agreements or termination of existing collaboration agreements;
- adverse results or delays in clinical trials being conducted by us or any collaborators;
- any intellectual property or other lawsuits involving us;

third-party sales of large blocks of our common stock;

sales of our common stock by our executive officers, directors or significant stockholders;

equity sales by us of our common stock to fund our operations;

the loss of any of our key scientific or management personnel;

FDA or international regulatory actions, such as matters related to the partial clinical hold placed on CUDC-427 by the FDA;

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.

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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, 2013, 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. 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.

We currently have on file with the SEC a universal shelf registration statement which allows us to offer and sell registered common stock, preferred stock and warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. For example, in July 2013 we entered into a sales agreement with Cowen pursuant to which, from time to time, we may offer and sell up to $30,000,000 of the common stock that was registered on this shelf registration statement through Cowen pursuant to one or more at the market offerings from which we have received gross proceeds of approximately $16,900,000 as of December 31, 2013. In addition, with our prior written approval, Cowen 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.

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

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

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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, 2013, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 31% of our outstanding common stock. As a result, these stockholders, if acting together, will be able to exert influence over the management and affairs of our company and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership could harm the market price of our common stock by:

delaying, deferring or preventing a change in control of our company;

impeding a merger, consolidation, takeover or other business combination involving our company; or

entrenching our management or the board of directors.

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.

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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	
Year ended December 31, 2012	**High**	**Low**
First Quarter	$ 5.65	$ 4.20
Second Quarter	$ 5.49	$ 4.40
Third Quarter	$ 5.51	$ 3.83
Fourth Quarter	$ 4.27	$ 2.98
Year ended December 31, 2013		
First Quarter	$ 3.68	$ 2.66
Second Quarter	$ 4.50	$ 2.96
Third Quarter	$ 4.63	$ 3.20
Fourth Quarter	$ 4.74	$ 2.44

(b) *Holders*. On March 6, 2014, the last reported sale price of our common stock on the NASDAQ Global Market was $2.95 and there were 238 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 common stock during the three months ended December 31, 2013.

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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, 2008 through December 31, 2013, 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, 2008 in our common stock and in each of the indices and, in each case, assumes reinvestment of all dividends.

	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12	12/31/13
CURIS INC.	100.00	433.33	264.00	624.00	457.33	376.00
NASDAQ COMPOSITE INDEX	100.00	144.88	170.58	171.30	199.99	283.39
NASDAQ PHARMACEUTICAL INDEX	100.00	104.90	109.55	125.16	172.74	284.56
NASDAQ BIOTECHNOLOGY INDEX	100.00	104.67	112.89	127.04	169.50	288.38

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ITEM 6. SELECTED FINANCIAL DATA

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,				
	2013	2012	2011	2010	2009
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenues:					
License and maintenance fees(1)	$ 10,000	$ 14,000	$ 14,300	$ 15,656	$ 7,809
Royalties	3,942	1,530			
Research and development(2)	1,060	1,442	463	344	781
Net revenues	15,002	16,972	14,763	16,000	8,590
Costs and expenses:					
Cost of royalty revenues	198	176			
Research and development.	12,927	15,493	13,693	11,373	9,933
In-process research and development.		9,500			
General and administrative.	11,293	10,423	8,273	10,265	8,702
Total costs and expenses	24,418	35,592	21,966	21,638	18,635
Loss from operations	(9,416)	(18,620)	(7,203)	(5,638)	(10,045)
Other income (expense):					
Interest and other income	165	150	100	627	222
Interest expense	(3,842)	(204)			
Change in fair value of warrants	771	2,257	(2,756)	576	
Total other income (expenses), net	(2,906)	2,203	(2,656)	1,203	222
Net loss	$ (12,322)	$ (16,417)	$ (9,859)	$ (4,435)	$ (9,823)
Basic and diluted net loss per common share	$ (0.15)	$ (0.21)	$ (0.13)	$ (0.06)	$ (0.15)
Weighted average common shares (basic and diluted)	82,339	79,059	76,352	74,959	65,061

	(in thousands) As of December 31,				
	2013	2012	2011	2010	2009
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 68,906	$ 58,701	$ 37,718	$ 40,380	$ 25,035
Working capital	53,607	52,873	34,717	37,608	23,347
Investment restricted	180	194	236	497	216
Total assets	80,591	69,768	48,180	50,649	36,099
Long-term obligations(3)	28,859	31,522	4,518	1,656	
Accumulated deficit	(760,827)	(748,505)	(732,088)	(722,229)	(717,793)
Total stockholders equity	45,174	34,267	39,876	45,518	33,052

(1) During the years ended December 31, 2013, 2012, 2011 and 2009, we recognized $10,000,000, $14,000,000, $14,000,000 and $6,000,000 of revenue for cash payments that we earned during each of 2013, 2012, 2011 and 2009, respectively, under our June 2003 Hedgehog pathway inhibitor collaboration

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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 years ended December 31, 2013 and 2012, we recognized $650,000 and $1,000,000, respectively, of research and development revenue for milestones that we earned under our November 2011 agreement with LLS.

(3) Long-term obligations are comprised of the following:

	(in thousands) As of December 31,			
	2013	2012	2011	2010
Long-term debt	$ 27,945	$ 29,839	$	$
Warrants	717	1,488	4,361	1,605
Deferred rent payments	197	195	157	51
Total long-term obligations	$ 28,859	$ 31,522	$ 4,518	$ 1,656

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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 drug development company seeking to develop novel, targeted drug candidates for the treatment of human cancers. We conduct our research and development programs both internally and through strategic collaborations. Internally, we are leveraging our experience in targeting signaling pathways in seeking to develop targeted drug candidates including CUDC-427 and CUDC-907. Our collaborators Genentech and Roche are commercializing Erivedge and our licensee Debiopharm is advancing the clinical development of Debio 0932.

On November 5, 2013, we received written notification from the FDA that our Phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until we provide the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. In February 2014, we responded to FDA s request for additional data and analysis and also submitted an amendment to the current study protocol. If the partial clinical hold is lifted by the FDA, we expect to re-initiate enrollment in the phase 1 trial and also expect to initiate additional studies with CUDC-427.

Proprietary Drug Candidates

CUDC-907. CUDC-907 is an orally bioavailable drug candidate designed to predominantly inhibit select classes of HDAC enzymes (primarily Classes I and IIB) and certain isoforms of PI3K (mainly PI3K- alpha, delta and beta). In January 2013, we initiated a phase 1 clinical trial in patients with advanced lymphoma or multiple myeloma. This first-in-human study is designed to assess the safety (including the maximum tolerated dose), pharmacokinetics, and anti-cancer activity of CUDC-907. In July 2013, we amended the protocol of the ongoing phase 1 study to include two additional dosing regimens, wherein oral CUDC-907 will be administered either two times per week or three times per week. Additionally, exploratory biomarkers will be assessed for the activity of CUDC-907.

We expect to complete the dose-escalation phase of this phase 1 study in the middle of 2014 and initiate enrollment in the expansion cohort(s) in patients with select malignancies in the second half of 2014. In addition to our ongoing phase 1 clinical study in advanced lymphomas and multiple myeloma patients, we are conducting preclinical studies with CUDC-907 in solid tumor models and expect that we will initiate additional studies using CUDC-907 in in patients with solid tumors later in 2014. In November 2011, we entered into an agreement with the Leukemia and Lymphoma Society, or LLS, relating to the development of CUDC-907.

CUDC-427. In 2012, we licensed from Genentech the exclusive, worldwide rights for the manufacture, development and commercialization of a small molecule Smac mimetic 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. Genentech will be entitled to milestone payments upon the first commercial sale of CUDC-427 in certain territories and a tiered low-to-mid single-digit royalty on net sales of CUDC-427, if any.

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IAP proteins are a family of functionally and structurally related proteins that promote cancer cell survival by inhibiting programmed cell death, a process also referred to as apoptosis. Using IAP proteins and other anti-apoptotic factors, cancer cells evade cell death 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 the TNF family. 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 1 clinical trial of CUDC-427 (previously GDC-0917), in which 42 patients with refractory solid tumors or lymphoma 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.

In July, 2013, we initiated an open label, multicenter phase 1 study of CUDC-427 in patients with advanced and refractory solid tumors or lymphomas. The study was designed to determine the maximum tolerated dose and recommended phase 2 dose of CUDC-427 administered as a single agent using a continuous, twice-daily treatment schedule. On November 5, 2013, we received written notification from the FDA that this phase 1 study of CUDC-427 had been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until we provide the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. In February 2014, we responded to the FDA s requests for additional information and also submitted an amendment to the current protocol. If the partial clinical hold is lifted by the FDA, we expect to re-initiate enrollment in the phase 1 trial and also expect to initiate additional studies with CUDC-427, including a clinical trial in combination with capecitabine in HER-2 negative breast cancer patients. Additionally, we anticipate testing CUDC-427 in selected patients with known alterations in certain genetic markers such as MALT lymphoma and other cancer indications, subject to FDA removing the partial clinical hold.

CUDC-101. In April 2013, we determined that we would discontinue enrolling patients in our phase 1 expansion trial of the intravenous formulation of CUDC-101, a drug candidate that was designed to target epidermal growth factor receptor and HDAC enzymes, and that the future development of CUDC-101 would be dependent on our ability to successfully develop an oral formulation of CUDC-101. Our efforts to develop an effective oral formulation with improved bioavailability have not resulted in significant improvements when compared to the intravenous formulation of CUDC-101. As a result, while we continue to explore possible collaboration or other mechanisms to further advance this molecule, at this time we no longer plan to make material investments in this program.

Our Collaborations

Erivedge® (vismodegib) capsule. Erivedge is a first-in-class orally-administered small molecule Hedgehog pathway inhibitor developed under collaboration with Genentech. Erivedge was discovered by Genentech and jointly validated by Genentech and Curis through a series of preclinical studies. 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. We are eligible to receive cash payments upon the successful achievement of specified clinical development and regulatory approval milestones, as well as royalties related to commercial sales of Erivedge.

In January 2012, the FDA approved Erivedge 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. In May 2013, Australia s TGA approved Erivedge and in July 2013 the European Commission granted conditional approval for the marketing of Erivedge in all 28 European Union member states. A conditional marketing authorization is granted to medicinal products with a positive benefit/risk

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assessment that satisfy an unmet medical need and whose availability results in a significant public health benefit. In addition to the United States, Australia and European Union, Erivedge is approved in several other countries and Roche has also filed several new drug applications for marketing registration with health agencies in other territories. Erivedge s regulatory approvals and Roche s submissions in other territories are based on positive clinical data from the ERIVANCE BCC study.

In addition to the lead indication of advanced BCC, Genentech evaluated Erivedge in a single-arm, three cohort phase 2 clinical trial to treat less advanced forms of BCC. Roche expects to present data from this study at the American Academy of Dermatology Annual Meeting in March 2014. Roche has also initiated a randomized, placebo controlled phase 2 study to investigate the efficacy of 12 weeks of Erivedge treatment (versus placebo) prior to surgery in previously untreated BCC. The primary endpoint of this study is the percentage change in BCC tumor area following 12 weeks of Erivedge or placebo therapy.

In October 2013 Roche also initiated a phase 1b/2 clinical trial to investigate the safety and efficacy of Erivedge in patients with relapsed/refractory AML, and relapsed/refractory high-risk MDS. In contrast to BCC, these two clinical conditions are driven by mechanisms that are not linked to mutations in the Hedgehog pathway. In addition to Genentech/ Roche sponsored studies, several third-party investigators are also conducting clinical trials with Erivedge.

Pursuant to the terms of our collaboration agreement with Genentech, we are entitled to a royalty on net sales of Erivedge that ranges from 5% to high single digits of global Erivedge sales, 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 or when there is no issued intellectual property covering Erivedge in a territory in which sales are recorded.

We recognized $3,942,000 of royalty revenue from Genentech s net sales of Erivedge during the year ended December 31, 2013 and have recognized an aggregate of $5,472,000 in royalty revenues since Erivedge was approved. As discussed below, royalty payments related to Erivedge service the outstanding debt and accrued interest of Curis Royalty owed to BioPharma-II, up to the quarterly caps for 2014 and 2015, and until the debt is fully repaid thereafter.

In December 2012, our wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan from BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that we may receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to us. As of December 31, 2013, Curis Royalty owed a total of $31,013,000, gross, to BioPharma-II comprised of principal and accrued interest.

We are also obligated to make payments to university licensors on royalties that Curis Royalty earns in all territories other than Australia in an amount that is equal to 5% of the royalty payments that Curis Royalty receives from Genentech for a period of 10 years from the first commercial sale of Erivedge, which occurred in February 2012. For royalties that we earn in from Roche s sales of Erivedge in Australia, we will be obligated to make payments to university licenses of 2% of Roche s direct net sales in Australia until expiration of the patent in April 2019, after which the amount will decrease to 5% of the royalty payments that we receive from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022. We recorded cost of royalty revenues of $198,000 during the year ended December 31, 2013 and have recorded an aggregate of $374,000 in cost of royalty revenues since Erivedge was approved.

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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.

In April 2010, Debiopharm initiated a phase 1 clinical trial to evaluate the safety of Debio 0932 given orally to patients with advanced solid tumors. In 2011, Debiopharm successfully advanced Debio 0932 through the dose escalation portion of this phase 1 study and determined 1000 mg daily to be the recommended dose for further development. In the beginning of 2012, Debiopharm advanced Debio 0932 into the phase 1b expansion portion of the study at this 1000 mg daily dose level. The primary objectives of this study were to further assess the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at the oral 1000 mg daily dose and to make a preliminary assessment of its anti-tumor activity. Debiopharm completed the phase 1b expansion portion of the study, enrolling approximately 30 patients with advanced solid tumors, including patients with NSCLC.

In August 2012, Debiopharm initiated the HALO phase 1/2 clinical trial of Debio 0932 in combination with various chemotherapy regimens in patients with stage IIIb or IV NSCLC without known EGFR mutations. In the phase 1 portion of this study, various doses of Debio 0932 are being investigated in combination with either cisplatin/pemetrexed or cisplatin/gemcitabine in treatment-naïve patients, and with docetaxel in previously treated patients. Once a recommended phase 2 dose of Debio 0932 in combination with the chemotherapy regimen(s) has been identified, Debiopharm expects to initiate the randomized, double-blind, placebo-controlled phase 2 portion of the study. The phase 2 portion of the HALO trial is expected to enroll eligible patients with NSCLC, who will be randomized to receive standard of care chemotherapy treatment in combination with either Debio 0932 or placebo. The primary objective of this study is to compare the effect of adding Debio 0932 to combination chemotherapy with cisplatin/pemetrexed and cisplatin/gemcitabine on the rate of progression-free survival at 6 months in first-line therapy of patients in this study population. Under our agreement with Debiopharm, we are eligible for our next milestone payment when Debiopharm treats its fifth patient in a phase 2 clinical trial, which we expect could occur in 2014. We have received $13,000,000 in milestone payments to-date from Debiopharm under this collaboration.

In October 2013, Debiopharm initiated an open-label, multicenter phase 1 dose-finding study of Debio 0932, in combination with everolimus, an inhibitor of mTOR, in patients with advanced or metastatic renal cell carcinoma, or RCC, who have been previously treated with a VEGF-directed tyrosine kinase inhibitor. This dose escalation study is designed to determine the safety and maximum tolerated dose of Debio 0932.

Liquidity

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our corporate collaborators, private and public 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 $760,827,000 as of December 31, 2013.

We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. We anticipate that existing capital resources as of December 31, 2013 should enable us to maintain current and planned operations into 2016. Our ability to continue funding our planned operations into and beyond this point 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.

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Key Drivers

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

- Genentech s ability to successfully commercialize Erivedge in advanced BCC;
- Genentech s effective use of results from the ongoing phase 2 clinical trial of Erivedge in patients with operable BCC, and positive results from the Erivedge clinical trial in AML and MDS patients;
- our ability to successfully plan, finance and complete current and planned clinical trials for CUDC-907 and CUDC-427, subject to the FDA removing the partial clinical hold; and
- Debiopharm s ability to advance Debio 0932 into later stages of clinical development.

In the longer term, a key driver to our success will be our ability, and the ability of any current or future collaborator or licensee, to successfully develop and commercialize additional product candidates.

Our current collaboration and license agreements are summarized as follows:

Genentech Hedgehog Pathway Inhibitor Collaboration. Under the terms of our collaboration agreement with Genentech, we granted Genentech an exclusive, global, royalty-bearing license, with the right to sublicense, to make, use, sell and import small molecule and antibody Hedgehog pathway inhibitors. The lead drug candidate being developed under this program is Erivedge. 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 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.

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 $56,000,000 as of December 31, 2013. 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 $3,942,000 and $1,530,000 in such revenue for sales of Erivedge during the years ended December 31, 2013 and 2012, respectively. Future royalty payments related to Erivedge will service the outstanding debt and accrued interest to BioPharma-II, up to the quarterly caps for 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, in patients with relapsed or refractory lymphomas and multiple myeloma. During the years ended December 31, 2013 and 2012, we earned milestone payments of $650,000 and $1,000,000, respectively, 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 future payments capped at 2.5 times the 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 to begin phase 1 clinical trials and the treatment of the fifth patient in these trials. We are eligible to receive up to an additional $77,000,000 if specified clinical development and regulatory approval objectives are met. We are also eligible to receive royalties if any products under the license agreement are successfully developed and commercialized. Subject to specified exceptions, we are entitled to a high single-digit to low double-digit royalty for net sales of Debio 0932 that are made directly by Debiopharm, escalating within this range with increasing product sales. We are entitled to a share of royalties that Debiopharm receives from a 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, 2013 should enable us to maintain current and planned operations into 2016.

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

In connection with the loan, we transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that we may receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to us. Under the terms of the loan, quarterly royalty payments received by Curis Royalty from Genentech will first be applied to pay (i) escrow fees payable by us pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) our royalty obligations to academic institutions, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by us enforcing our right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject to caps of $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 the remaining amounts above the caps, if any, and we remain entitled to receive any contingent payments upon achievement of clinical development objectives. In 2016, there are no caps to the amounts Curis Royalty will be required to make to BioPharma-II. Curis Royalty retains the right to royalty payments related to sales of Erivedge following repayment of the loan.

The final maturity date of the loan will be the earlier of 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

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upon the occurrence of an event of default as defined in the credit agreement. During 2013, Curis Royalty began making payments to BioPharma-II upon receipt of the Erivedge royalties. The amounts paid through December 31, 2013 were less than the interest accrued through the repayment dates resulting in a total of $714,000 being added to the outstanding principal. As of December 31, 2013, Curis Royalty owed a total of $31,013,000, gross, to BioPharma-II comprised of principal and accrued interest.

Revenue. We do not expect to generate any revenues from our direct sale of products for several years, if ever. Substantially all of our revenues to date have been derived from license fees, research and development payments, and other amounts that we have received from our strategic collaborators and licensees, including royalty payments. For the year ended December 31, 2013, milestone and royalty payments from Genentech accounted for $14,233,000, or 95%, 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 continue 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, we expect that all of such royalty revenues will be used by our wholly-owned subsidiary, Curis Royalty, to pay principal and interest under the loan that Curis Royalty received from BioPharma II, subject to quarterly caps, until such time as the loan is fully repaid. We currently estimate that the debt will be repaid in the first half of 2017. However, the actual repayment period could vary materially from our estimate to the extent that royalty payments we receive are lower than our current estimates, which could arise due to factors beyond our control, such as due to competitive factors, decreased market acceptance, a failure by Genentech and/or Roche to obtain required regulatory approvals, and other factors described under Part I, Item 1A Risk Factors.

We could receive additional milestone payments from Genentech, Debiopharm, and LLS, provided the respective programs meet contractually-specified development and regulatory objectives. In May 2013, Erivedge was approved for marketing registration by Australia s TGA for the treatment of adult patients with metastatic or locally advanced BCC. The Australian approval resulted in a $4,000,000 milestone payment to us in the second quarter of 2013. Additionally, in July 2013, Erivedge received conditional approval from the European Commission for the marketing of Erivedge in all 28 European Union member states. As a result of this conditional approval, we earned a $6,000,000 milestone payment from Genentech, which was received in the third quarter of 2013. Erivedge is also currently being reviewed for potential marketing approval by health authorities in several additional territories.

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 and Comprehensive Loss. 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 earn in from Roche s sales of Erivedge in Australia, we will be obligated to make payments to university licenses of 2% of Roche s direct net sales in Australia until expiration of the patent in April 2019, after which the amount will decrease to 5% of the royalty payments that we receive from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022.

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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.

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

Drug candidate	Primary Disease	Collaborator/Licensee	Status
Dual HDAC and PI3K Inhibitor			
- CUDC-907	Advanced lymphomas and multiple myeloma	Internal development/LLS	Phase 1
Antagonist of IAP Proteins			
- CUDC-427	Advanced solid tumor & lymphomas including potential expansion cohort of ovarian and fallopian tube derived cancers	Internal development	Phase 1* partial clinical hold since November 5, 2013
Hedgehog Pathway Inhibitor			
- Erivedge	Advanced BCC	Genentech (Roche)	Approved in US, EU, Australia and others; Regulatory submissions/ approvals pending in certain other territories
- Erivedge	Operable Nodular BCC	Genentech (Roche)	Completed Phase 2
- Erivedge	Operable BCC	Genentech (Roche)	Phase 2
- Erivedge	Relapsed/Refractory AML and High Risk MDS	Roche	Phase 1b/2
HSP90 Inhibitor			
- Debio 0932	Advanced NSCLC	Debiopharm	Phase 1-2
- Debio 0932	Advanced renal cell carcinoma	Debiopharm	Phase 1

A first Phase 1 clinical trial was conducted by Genentech in advance solid tumors and lymphomas prior to Curis acquisition of CUDC-427. Curis initiated a Phase 1 trial in 2015 which is currently on FDA clinical hold.

Because of the early stages of development of most of our programs other than Erivedge in advanced BCC, 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 other risks and uncertainties associated with developing drugs which may affect our and our collaborators future results, including:

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

- the results of future preclinical studies and clinical trials;

the cost and timing of regulatory approvals and maintaining compliance with regulatory requirements;

the cost and timing of establishing sales, marketing and distribution capabilities;

the cost of establishing clinical and commercial supplies of our drug candidates and any products that we may develop;

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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.

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.

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

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*.

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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.

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. If the license is considered to not have stand-alone value, 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.

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In addition, if we are involved in a steering committee as part of a multiple element arrangement, 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.

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) our 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 our 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 Curis Royalty s 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.

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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 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 account for stock-based compensation transactions be accounted for using a grant-date fair-value-based method under FASB Codification Topic 718, *Compensation Stock Compensation*.

We have recorded employee and director stock-based compensation expense of $2,651,000, $3,269,000 and $1,642,000 for the years ended December 31, 2013, 2012 and 2011, respectively. We estimate that we will record approximately $2,950,000, in stock-based compensation expense in 2014. We have granted and expect that we may grant additional options in 2014 that could increase the amount of stock-based compensation ultimately recognized. The amount of the incremental employee stock-based compensation expense attributable to 2014 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.

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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 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.

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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 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 2013, 2012 and 2011, 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 2013, 2012 and 2011.

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, 2013 and 2012

Revenues

Total revenues are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2013	**2012**	
Revenues:			
Research and development			
Genentech	$ 291,000	$ 363,000	(20%)
LLS	650,000	1,000,000	(35%)
Other	119,000	79,000	51%
Subtotal	1,060,000	1,442,000	(26%)
License fees from Genentech	10,000,000	14,000,000	(29%)
Royalty revenues from Genentech	3,942,000	1,530,000	158%
Total revenues	$ 15,002,000	$ 16,972,000	(12%)

Total revenues were $15,002,000 and $16,972,000 for the years ended December 31, 2013 and 2012, respectively. The decrease in 2013 total revenues of $1,970,000, or 12%, as compared to the prior year was due to a decrease in license fee revenues from Genentech, offset by an increase in royalty revenues from Genentech and Roche s net sales of Erivedge. 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. Our license fee revenues of $10,000,000 for the year ended December 31, 2013 are related to payments we received from Genentech upon marketing approvals of Erivedge in Europe and Australia. In addition, the revenues recognized under our agreement with LLS for achievement of clinical development objectives related to our phase 1 clinical trial of CUDC-907 decreased by $350,000 for the year ended December 31, 2013.

Royalty revenues from Genentech and Roche s net sales of Erivedge during the year ended December 31, 2013 increased by $2,412,000, or 158%, as compared to the year ended December 31, 2012. We expect that all Erivedge royalty revenues will be used by Curis Royalty to pay principal and interest under the loan that Curis Royalty received from BioPharma II, subject to quarterly caps, until such time as the loan is fully repaid.

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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. 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 phase 2 clinical trials. 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 were $198,000 and $176,000 for the year ended December 31, 2013 and 2012, respectively. The increase in cost of royalty revenues during 2013 was due to an increase in payments to our university licensors during 2013 resulting from an increase in royalty revenues from Genentech and Roche s net sales of Erivedge. Cost of royalty revenues for the year ended December 31, 2012 also included a $100,000 one-time cash payment paid to a university licensor upon the first commercial sale of Erivedge.

Operating Expenses

Research and development expenses are summarized as follows:

Research and Development Program	For the Year Ended December 31, 2013	2012	Percentage Increase/ (Decrease)
CUDC-907	$ 4,424,000	$ 4,046,000	9%
CUDC-427	5,078,000	11,000	46,064%
CUDC-101	1,310,000	4,497,000	(71%)
Erivedge	158,000	151,000	5%
Debio 0932	36,000	57,000	(37%)
Other discovery research programs	542,000	3,541,000	(85%)
Sublicense fees incurred on development and regulatory milestones under our Genentech collaboration	500,000	2,114,000	(76%)
Stock-based compensation	879,000	1,075,000	(18%)
Total research and development expenses	$ 12,927,000	$ 15,492,000	(17%)

Total research and development expenses were $12,927,000 for the year ended December 31, 2013 as compared to $15,492,000 for 2012. Our research and development expenses decreased by $2,565,000, or 17%, for the year ended December 31, 2013, as compared to the prior year primarily due to decreases in spending on CUDC-101, our discovery research programs and Erivedge-related payments to sublicensors, offset in part by increased spending on CUDC-427 that was exclusively licensed from Genentech in November 2012.

Spending related to our CUDC-101 and discovery research programs decreased by $6,186,000 during the year ended December 31, 2013 as compared to 2012, primarily due to our decisions to discontinue clinical development of CUDC-101 while continuing to research oral formulations of this molecule and to allocate our internal resources, primarily personnel, to our clinical development programs, CUDC-907 and CUDC-427.

In addition, sublicense fees decreased by $1,614,000 during the year ended December 31, 2013 as compared to the prior year, primarily resulting from one-time sublicense fees and the one-time issuance to a university licensor of an aggregate of 200,000 shares of our common stock in connection with Erivedge s FDA approval, Roche s NDA filing in Australia and our receipt of related milestone payments during the year ended December 31, 2012.

Stock-based compensation also decreased $196,000 during the year ended December 31, 2013 from the prior year, primarily related to a decrease in the expense recognized on unvested non-employee stock options that are marked-to-market at each quarterly reporting period. Fluctuations in our stock price will result in fluctuations in the related expense.

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We expect that a majority of our research and development expenses for the foreseeable future will be incurred in support of our efforts to advance CUDC-907 and, if the FDA lifts the partial clinical hold, CUDC-427. In addition, we will be obligated to pay sublicense fees for any milestone payments we may receive upon achievement of specified regulatory objectives and 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. We will also be obligated to pay LLS up to 2.5 times the amount of funding that we have received from LLS in support of our development of CUDC-907 should CUDC-907 be partnered or commercialized on or after completion of a phase 2a trial. As of December 31, 2013, we have received $1,650,000 under our agreement with LLS, which would result in a maximum payment to LLS of $4,125,000. If our developments efforts are successful, we anticipate that we would receive additional payments from LLS and that our corresponding potential obligation would increase accordingly.

We recorded in-process research and development expenses of $9,500,000 for the year ended December 31, 2012 which represents 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)
	2013	2012	
Personnel	$ 3,491,000	$ 2,538,000	38%
Occupancy and depreciation	353,000	515,000	(31%)
Legal services	2,496,000	2,521,000	(1%)
Consulting and professional services	1,548,000	1,233,000	26%
Insurance costs	330,000	268,000	23%
Other general and administrative expenses	953,000	799,000	19%
Stock-based compensation	2,123,000	2,549,000	(17%)
Total general and administrative expenses	$ 11,294,000	$ 10,423,000	8%

General and administrative expenses were $11,294,000 and $10,423,000 for the years ended December 31, 2013 and 2012, respectively. General and administrative expenses increased in 2013, primarily due to an increase in personnel costs and an increase in professional services, including audit fees and business development consulting services. In addition, other general and administrative spending increased $154,000 over the prior year period, which is comprised of travel, banking and listing fees and other operating expenses.

Offsetting these increases, stock-based compensation expense decreased $426,000 from the prior year as a result of a decrease in the grant-date fair value of options issued during the year ended December 31, 2013 as 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 was estimated using a Black-Scholes option pricing model. 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 income statement. Expected volatilities used in the models were based on our historical volatility commensurate with the term of the warrants.

We recorded the fair value of the warrants at December 31, 2013 as $717,000 using this model with the following assumptions: expected volatility of 65%, risk free interest rate of 0.2%, expected life of 1.1 years and no dividends. We recorded the fair value of the warrants at December 31, 2012 as $1,488,000 using this model

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with the following assumptions: expected volatility of 58%, risk free interest rate of 0.3%, expected life of 2.1 years and no dividends. We recorded other income of $771,000 and $2,257,000 for the years ended December 31, 2013 and 2012, respectively, related to changes in the assumptions used in the valuation of the warrants, including changes in our stock price, during the respective periods. During the year ended December 31, 2012, warrants to purchase 237,301 shares of our common stock were exercised.

Other Expense (Income)

For the years ended December 31, 2013 and 2012, interest expense was $3,842,000 and $204,000, respectively. The increase in 2013 was related to an increase in the interest accrued on Curis Royalty s outstanding debt with BioPharma-II. Curis Royalty s debt with the BioPharma-II was not incurred until the December 2012.

For the years ended December 31, 2013 and 2012, interest income was $165,000 and $150,000, respectively.

Net Loss Applicable to Common Stockholders

As a result of the foregoing, we incurred a net loss applicable to common stockholders of $12,322,000 for the year ended December 31, 2013, as compared to $16,417,000 for the year ended December 31, 2012.

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	
Revenues:			
Research and development			
Genentech	$ 363,000	$ 388,000	(6%)
LLS	1,000,000		100%
Other	79,000	75,000	5%
Subtotal	1,442,000	463,000	211%
License fees			
Genentech	14,000,000	14,000,000	%
Other		300,000	(100%)
Subtotal	14,000,000	14,300,000	(2%)
Royalty revenues from Genentech	1,530,000		100%
Total Revenues	$ 16,972,000	$ 14,763,000	15%

Total revenues were $16,972,000 and $14,763,000 for the years ended December 31, 2012 and 2011, respectively. The increase in total revenues in 2012 as compared to the prior year was due 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.

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Our license fee revenues of $14,000,000 for the year ended December 31, 2012 were 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.

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, 2012	2011	Percentage Increase/ (Decrease)
CUDC-907	$ 4,046,000	$ 3,201,000	26%
CUDC-427	11,000		100%
CUDC-101	4,497,000	4,289,000	5%
Erivedge	151,000	192,000	(21%)
Debio 0932	57,000	45,000	27%
Other discovery research programs	3,541,000	4,604,000	(23%)
Sublicense fees incurred on development and regulatory milestones under our 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%
Total research and development expenses	$ 15,492,000	$ 13,693,000	13%

Total research and development expenses were $15,492,000 for the year ended December 31, 2012, as compared to $13,693,000 for 2011. The increase in research and development expenses during 2012 was primarily due to a $1,414,000 increase in sublicense fees paid during 2012 to universities as a result of the receipt of contingent payments from Genentech for the achievement of regulatory objectives related to Erivedge, including a one-time issuance of an aggregate of 200,000 shares of our common stock to two university licensors with a fair value of $964,000, as well as 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 phase 1 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 during 2012 on our CUDC-101 phase 1b trial, as the last patient on trial was treated in October 2011. Further offsetting these increases, spending on our other discovery research programs decreased $1,063,000 during 2012 as compared to 2011 as our internal resources were primarily allocated to CUDC-101 and CUDC-907.

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.

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We recorded in-process research and development expenses of $9,500,000 for the year ended December 31, 2012, which 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 were $10,423,000 and $8,272,000 for the years ended December 31, 2012 and 2011, respectively. The 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. As a result of revaluing the warrants issued in January 2010, 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.

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.

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In December 2012, our wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan at an annual interest rate of 12.25% pursuant to a credit agreement with BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that we may receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to us. The final maturity date of the loan will be the earlier of 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. Payments to BioPharma-II through December 31, 2013 totaled $2,928,000 and covered only a portion of the interest accrued on the loan. As a result, $714,000 of the unpaid and accrued interest through December 31, 2013 has been capitalized and added to the principal portion of the loan. As of December 31, 2013, Curis Royalty owed a total of $31,013,000, gross of issuance costs, to BioPharma-II comprised of principal and accrued interest.

For the years ended December 31, 2013 and 2012, we received aggregate milestone payments totaling $24,000,000 under our collaboration with Genentech. In addition, we received royalty revenues during 2012 in connection with Genentech s net sales of Erivedge. Royalty revenues earned subsequent to December 2012 are being used to repay Curis Royalty s outstanding principal and interest under the loan due to BioPharma-II, subject to specified quarterly caps. Curis Royalty will be entitled to receive and distribute to Curis remaining royalty and royalty-related amounts in excess of the foregoing caps, if any. We also remain entitled to receive any contingent payments upon achievement of clinical development objectives and royalty payments related to sales of Erivedge following repayment of the loan. Upon earning any such payments, as well as on royalties that are earned in any territory other than Australia, we are required to make payments to certain university licensors totaling 5% of these amounts. For royalties that we earn in from Roche s sales of Erivedge in Australia, we will be obligated to make payments to university licenses of 2% of Roche s direct net sales in Australia until expiration of the patent in April 2019, after which the amount will decrease to 5% of the royalty payments that we receive from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022.

In July 2013, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may sell from time to time up to $30,000,000 of our common stock through an at-the-market equity offering program under which Cowen will act as sales agent. Subject to the terms and conditions of the sales agreement, Cowen may sell the common stock by methods deemed to be an at-the-market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on the NASDAQ Global Market, on any other existing trading market for the common stock or to or through a market maker other than on an exchange. The aggregate compensation payable to Cowen shall be 3% of the gross sales price of the common stock sold by Cowen pursuant to the sales agreement. Through December 31, 2013, we have sold 3,850,206 shares of common stock pursuant to this sales agreement for proceeds of $16,246,000, net of all issuance costs.

At December 31, 2013, our principal sources of liquidity consisted of cash, cash equivalents, and investments of $68,906,000, excluding our restricted investments of $180,000. 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.

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Net cash used in operating activities was $9,540,000 during the year ended December 31, 2013, primarily the result of our net loss for the period of $12,322,000, offset by non-cash charges totaling $3,286,000 consisting of stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense and depreciation and amortization. Changes in certain operating assets and liabilities had offsetting impacts on operating cash during the year ended December 31, 2013, and an increase of $569,000 in our accounts receivable, primarily related to quarterly royalties earned on the sale of Erivedge, also decreased operating cash. During the year ended December 31, 2013, we received $14,883,000 in milestone and royalty payments under our collaborations with Genentech and LLS. Offsetting these cash receipts, we incurred operating and other expenses of $27,324,000.

Cash used in operating activities of $15,193,000 for the year ended December 31, 2012 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 2012. 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.

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 $13,618,000 and $23,003,000 for years ended December 31, 2013 and 2012, respectively, resulting primarily from net investment activity from purchases and sales or maturities of investments for the respective periods. The increase in investments during the years ended December 31, 2013 and 2012 was the result of increases in cash receipts. In addition, during the years ended December 31, 2013 and 2012, we reduced our restricted investments, resulting in an increase in our available cash for the periods of $14,000 and $42,000, respectively. These increases in cash were offset by purchases of research equipment totaling $153,000 and $105,000 during the years ended December 31, 2013 and 2012, respectively.

Financing activities provided cash of $20,001,000 and $35,825,000 for the years ended December 31, 2013 and 2012, respectively. We received $16,246,000 in net proceeds from sales of common stock under our sales agreement with Cowen for the year ended December 31, 2013. We also received proceeds of $4,016,000 from the exercise of stock options during the year ended December 31, 2013. These proceeds were offset by the payment of debt issuance costs of $261,000 related to Curis Royalty s financing transaction with BioPharma-II.

Cash provided from financing activities during the year ended December 31, 2012 was primarily related to the debt financing transaction with BioPharma-II, that provided proceeds of $30,000,000, marginally offset by related issuance costs of $160,000. The exercise of stock options and warrants and purchases of common stock under our employee stock purchase plan provided additional cash of $5,106,000 for the year ended December 31, 2012. We also received $879,000 in net proceeds from sales of common stock under our prior at-the-market sales agreement with McNicoll, Lewis & Vlak, LLC for the year ended December 31, 2012.

Funding Requirements

We have incurred significant losses since our inception. As of December 31, 2013, we had an accumulated deficit of approximately $760,827,000. 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 and CUDC-907, and to fund our general and administrative costs and expenses.

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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 Curis Royalty s obligation to remit certain royalties to BioPharma-II). We expect that our only source of cash flows from operations for the foreseeable future will be:

- up-front license payments and research and development funding 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 Curis Royalty s obligation to remit certain royalties to BioPharma-II.

We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of us receiving payments under such collaborations is highly uncertain. In addition, for the foreseeable future, we will only receive royalties under our collaboration agreement with Genentech to the extent net sales are generated at a level sufficient to derive royalties in excess of Curis Royalty s obligation to remit such royalties to BioPharma-II in repayment of the loan.

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

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

We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at December 31, 2013, should enable us to maintain current and planned operations into 2016. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing, many of which are outside our control, including the following:

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

the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates;

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.

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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
- 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.

Contractual Obligations

As of December 31, 2013 we had contractual obligations and other commitments, including Curis Royalty s credit agreement with BioPharma-II, an operating lease related to our facility, research services agreements, consulting agreements, and license agreements, as follows:

		Payment Due By Period (amounts in 000 s)			
	Total	Less than One Year	One to Three Years	Three to Five Years	More than Five Years
Debt obligations under credit agreement(1)	$ 39,841	$ 6,479	$ 26,656	$ 6,706	$
Operating lease obligations(2)	2,713	627	1,327	759	
Outside service obligations(3)	490	356	134		
Licensing obligations(4)	182	173	9		
Total future obligations	$ 43,226	$ 7,635	$ 28,126	$ 7,465	$

(1) As of December 31, 2013, the outstanding balance, including interest, of the debt was $31,013,000. The above amounts reflect management s estimates of repayments, including accrued interest payments, based on the terms of Curis Royalty s credit facility with BioPharma-II and assumptions of future Erivedge royalties as of December 31, 2013. 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) We are party to a 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 $2,713,000. 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.

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(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, 2013. 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, 2013. 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 sublicensors related to future development milestones would total $2,950,000, or 5%, if all of the $59,000,000 in remaining milestones under our June 2003 Genentech collaboration are achieved. 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, 2013.

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 2013, the FASB issued an accounting standards update clarifying the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The updated guidance requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carryforward when settlement of the liability for an unrecognized tax benefit in this manner is available. The update is effective prospectively for reporting periods beginning after December 15, 2013, and early adoption and retrospective adoption are permitted. The adoption of this guidance is not expected to have an impact on the Company s 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, 2013, 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, 2013. In making this assessment our management used the criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO.

Based on our assessment, management concluded that, as of December 31, 2013, our internal control over financial reporting is effective based on the criteria established in *Internal Control Integrated Framework* issued by COSO.

The effectiveness of our internal control over financial reporting as of December 31, 2013 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, who has issued an attestation report on 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, stockholders equity and cash flows present fairly, in all material respects, the financial position of Curis, Inc. and its subsidiaries at December 31, 2013 and December 31, 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 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, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* 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 Management s Annual Report on Internal Control over Financial Reporting appearing under 9A. 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, 2014

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CURIS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	December 31, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,591,487	$ 12,747,709
Investments	48,588,135	42,791,689
Short-term investment restricted	13,877	13,877
Accounts receivable	1,477,188	908,064
Prepaid expenses and other current assets	495,260	390,564
Total current assets	60,165,947	56,851,903
Property and equipment, net	445,655	434,168
Long-term investments	10,726,685	3,162,025
Long-term investment restricted	166,487	180,405
Goodwill	8,982,000	8,982,000
Other assets	104,034	157,848
Total assets	$ 80,590,808	$ 69,768,349
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,036,864	$ 2,504,270
Accrued liabilities	1,911,479	1,474,556
Current portion of long-term debt, net	2,610,174	
Total current liabilities	6,558,517	3,978,826
Long-term debt, net	27,945,186	29,838,925
Warrants	716,786	1,488,179
Other long-term liabilities	196,734	194,921
Total liabilities	35,417,223	35,500,851
Commitments (Note 8)		
Stockholders Equity:		
Common stock, $0.01 par value 225,000,000 and 125,000,000 shares authorized at December 31, 2013 and 2012, respectively; 87,081,862 shares issued and 85,859,016 shares outstanding at December 31, 2013; and 81,065,488 shares issued and 80,017,781 shares outstanding at December 31, 2012	870,819	810,655
Additional paid-in capital	806,660,340	782,837,507
Treasury stock (at cost, 1,222,846 shares and 1,047,707 shares at December 31, 2013 and 2012, respectively)	(1,524,029)	(891,274)
Accumulated deficit	(760,826,561)	(748,504,549)
Accumulated other comprehensive (loss)/income	(6,984)	15,159
Total stockholders equity	45,173,585	34,267,498
Total liabilities and stockholders equity	$ 80,590,808	$ 69,768,349

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

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CURIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,		
	2013	**2012**	**2011**
Revenues:			
License fees	$ 10,000,000	$ 14,000,000	$ 14,300,000
Royalties	3,942,136	1,529,644	
Research and development	1,059,896	1,442,347	462,580
Total revenues	15,002,032	16,971,991	14,762,580
Costs and Expenses:			
Cost of royalties	197,796	176,482	
Research and development	12,926,834	15,492,302	13,692,659
In-process research and development		9,500,000	
General and administrative	11,293,811	10,423,014	8,272,424
Total costs and expenses	24,418,441	35,591,798	21,965,083
Loss from operations	(9,416,409)	(18,619,807)	(7,202,503)
Other Income (Expense):			
Interest income	164,650	149,937	100,034
Interest expense	(3,841,646)	(204,167)	
Change in fair value of warrant liability	771,393	2,257,130	(2,756,426)
Total other (expense) income	(2,905,603)	2,202,900	(2,656,392)
Net loss	$ (12,322,012)	$ (16,416,907)	$ (9,858,895)
Net Loss per Common Share (Basic and Diluted)	$ (0.15)	$ (0.21)	$ (0.13)
Weighted Average Common Shares (Basic and Diluted)	82,339,493	79,059,153	76,351,856
Net Loss	$ (12,322,012)	$ (16,416,907)	$ (9,858,895)
Other comprehensive loss, net of tax:			
Unrealized loss on marketable securities	(22,143)	(18,806)	(11,397)
Comprehensive loss	$ (12,344,155)	$ (16,435,713)	$ (9,870,292)

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

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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/(Loss)	Total Stockholders Equity
	Shares	Amount						
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 the Company s ATM agreement (see Note 9), net of $128,155 in ATM issuance costs	1,361,492	13,615	2,442,866					2,456,481
Recognition of employee stock-based compensation			1,641,830					1,641,830
Non-employee stock-based compensation expense, including mark-to-market			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 9), 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
Non-employee stock-based			355,222					355,222

compensation expense, including mark-to-market							
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
Issuances of common stock upon the exercise of stock options, for purchases under the ESPP, and pursuant to sales of shares under the Company s ATM agreement (see Note 9), net of $641,052 in ATM issuance costs	6,191,513	60,164	20,820,592				20,880,756
Repurchase of Company common stock (see Note 2(i))	(175,139)			(632,755)			(632,755)
Recognition of employee stock-based compensation			2,651,152				2,651,152
Non-employee stock-based compensation expense, including mark-to-market			351,089				351,089
Other comprehensive loss						(22,143)	(22,143)
Net loss					(12,322,012)		(12,322,012)
Balance, December 31, 2013	87,081,862	$ 870,819	$ 806,660,340	$ (1,524,029)	$ $ (760,826,561)	$ (6,984)	$ 45,173,585

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

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CURIS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2013	**2012**	**2011**
Cash Flows from Operating Activities:			
Net loss	$ (12,322,012)	$ (16,416,907)	$ (9,858,895)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	141,522	126,537	107,396
Stock-based compensation expense	3,002,241	3,623,911	1,772,111
Issuance of common stock to licensees		964,000	
Change in fair value of warrant liability	(771,393)	(2,257,130)	2,756,426
Amortization of debt issuance costs	104,842	5,769	
Non-cash interest (income)/expense	95,197	(434,763)	246,122
Non-cash interest on debt	713,968		
Gain on sale of fixed assets and equipment			(77,068)
Changes in operating assets and liabilities:			
Accounts receivable	(569,124)	(865,997)	50,304
Prepaid expenses and other assets	(116,639)	40,959	24,111
Accounts payable and accrued and other liabilities	181,821	20,316	416,196
Total adjustments	2,782,435	1,223,602	5,295,598
Net cash used in operating activities	(9,539,577)	(15,193,305)	(4,563,297)
Cash Flows from Investing Activities:			
Purchases of investments	(65,827,658)	(69,153,956)	(42,136,949)
Sales/maturities of investments	52,349,212	46,214,044	51,834,854
Decrease in restricted cash/investments	13,918	41,632	261,090
Expenditures for property and equipment	(153,009)	(104,975)	(260,405)
Proceeds from sale of equipment			77,068
Net cash (used in)/provided by investing activities	(13,617,537)	(23,003,255)	9,775,658
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock associated with offerings, net of issuance costs (see Note 9)	16,245,984	879,080	288,817
Proceeds from issuance of common stock under the Company s share-based compensation plans and warrant exercises	4,016,383	5,105,699	1,792,003
Payment of debt issuance costs	(261,475)	(160,240)	
Proceeds from debt		30,000,000	
Net cash provided by financing activities	20,000,892	35,824,539	2,080,820
Net (decrease)/increase in cash and cash equivalents	(3,156,222)	(2,372,021)	7,293,181
Cash and cash equivalents, beginning of period	12,747,709	15,119,730	7,826,549
Cash and cash equivalents, end of period	$ 9,591,487	$ 12,747,709	$ 15,119,730
Supplemental cash flow data:			
Cash paid for interest	$ 2,913,999	$	$

Non-cash items:			
Treasury stock	$ 632,755	$	$
Receivable for issuances of common stock	$	$ 14,366	$ 375,661
Unpaid debt issuance costs	$	$ 261,475	$

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. is an oncology-focused drug development company seeking to develop novel, targeted drug candidates for the treatment of human cancers. As used throughout these consolidated financial statements, the term the Company refers to the business of Curis, Inc. and its wholly owned subsidiaries, except where the context otherwise requires, and the term Curis refers to Curis, Inc.

The Company conducts its research and development programs both internally and through strategic collaborations. The Company is leveraging its experience in targeting signaling pathways in seeking to develop targeted drug candidates including CUDC-427, a small molecule antagonist of the inhibitor of apoptosis, or IAP, proteins, which is currently subject to a U.S. Food and Drug Administration, or FDA, partial clinical hold, and CUDC-907, a dual histone deacetylase, or HDAC, and phosphoinostide-3 kinase, or PI3K, inhibitor. Erivedge®, the first and only approved medicine for the treatment of advanced basal cell carcinoma, or BCC, is being 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 Curis and Genentech. The Company s licensee Debiopharm is advancing the clinical development of the heat shock protein 90, or HSP90, inhibitor, Debio 0932.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any products that are successfully developed and commercialized would be used in the health care industry and would be regulated in the United States by the FDA and in overseas markets by similar regulatory authorities.

The Company is subject to risks common to companies in the biotechnology industry as well as 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; the Company s ability to advance and expand its research and development programs, including whether the FDA lifts the partial clinical hold placed on CUDC-427; the Company s ability to obtain adequate financing to fund its operations; the ability of the Company s wholly owned subsidiary, Curis Royalty, LLC, or Curis Royalty, to satisfy the terms of its loan agreement with BioPharma Secured Debt Fund II Sub, S.à r.l., a Luxembourg limited liability company managed by Pharmakon Advisors, or BioPharma-II; the Company s ability to obtain and maintain necessary intellectual property protection; development by the Company s competitors of new or better technological innovations; dependence on key personnel; the Company s ability to comply with regulatory requirements; and the Company s ability to execute on its overall business strategies.

The Company s future operating results will largely depend on the 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: Roche and Genentech s ability to successfully commercialize Erivedge; positive results in Genentech s ongoing clinical trials; the timing, outcome and cost of the Company s preclinical studies and clinical trials for its drug candidates; whether or not the FDA removes the partial clinical hold on CUDC-427; 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 and investments at December 31, 2013 should enable it to maintain current and planned operations for the foreseeable future. The Company s ability to continue funding its planned operations beyond this period is dependent upon, among other things, the success of its collaborations with Genentech, Debiopharm and the Leukemia & Lymphoma Society, or LLS, including its receipt of additional contingent cash payments under these collaborations; its ability to control expenses and its ability to raise additional funds through equity or

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debt financings, new collaborations or other sources of financing. The Company may not be able to successfully raise additional funds or enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations is highly uncertain. If the Company is unable to obtain adequate financing, the Company may be required to reduce or delay spending on its research and/or development programs.

(2) 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 revenue recognition, including estimates of 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 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 (see Note 7), 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, 2013, 2012 and 2011.

(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 best 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 the undelivered item.

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 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. If the license is considered to not have stand-alone value, 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, 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.

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.

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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 Company 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 Company 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 recognized as revenue as 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.

Royalty Revenue

Since the first quarter of 2012, the Company has recognized royalty revenues related to Genentech s and Roche s sales of Erivedge. 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 7). However, Erivedge royalties will service Curis Royalty s debt to BioPharma-II, and only amounts in excess of certain quarterly repayment caps, if any, will be available to the Company for use in operations.

Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as short term deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be

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recognized during the year ending December 31, 2014 would be classified as long-term deferred revenue. As of December 31, 2013 and 2012, the Company had no amounts classified as short-term or long-term deferred revenue.

Summary

During the years ended December 31, 2013, 2012 and 2011, total gross revenues from the Company s collaborators as a percent of total gross revenues of the Company were as follows:

	Year Ended December 31,		
	2013	2012	2011
Genentech	95%	94%	97%
LLS	4%	6%	%

(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 royalty revenue 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.

(e) CASH EQUIVALENTS 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 short-term investments are marketable securities with original maturities of greater than three months from the date of purchase, but less than twelve months from the balance sheet date, and long-term investments are marketable securities with original maturities of greater than twelve months from the balance sheet. Marketable securities consist of commercial paper, corporate bonds and notes, and government obligations. All of the Company s investments 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.

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The amortized cost, unrealized losses and fair value of short-term investments available-for-sale as of December 31, 2013 with maturity dates ranging between one and twelve months and with a weighted average maturity of 4.7 months are as follows:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Corporate bonds and notes	$ 47,091,593	$ 9,036	$ (15,476)	$ 47,085,153
US government and municipal obligations	501,170	10		$ 501,180
Total investments	$ 47,592,763	$ 9,046	$ (15,476)	$ 47,586,333

In addition, a certificate of deposit in the amount of $1,001,802 that the Company held as of December 31, 2013 was included within short-term investments in the consolidated balance sheet but is excluded from the table above as it was not deemed to be a security.

As of December 31, 2013, the Company also recorded long-term investments of $10,726,685 on its Consolidated Balance Sheet. This amount is comprised of corporate and government-secured debt securities with maturities ranging from January 2015 to May 2015 with a weighted average maturity of 14.3 months and with amortized cost totaling $10,727,958, less unrealized net losses of $1,273.

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:

	Amortized Cost	Unrealized Gain	Fair Value
Corporate bonds and notes	$ 42,775,952	$ 15,737	$ 42,791,689
Total investments	$ 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.

(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.

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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 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 9, 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, 2013 and 2012 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, 2013 and 2012.

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
As of December 31, 2013:				
Cash equivalents				
Money market funds	$ 5,535,716	$	$	$ 5,535,716
Corporate commercial paper, bonds and notes		1,749,983		1,749,983
Municipal bonds		1,110,000		1,110,000
Short- and long-term investments				
US government obligations		1,151,932		1,151,932
Corporate commercial paper, stock, bonds and notes	20,176,154	36,984,932		57,161,086
Total assets at fair value	$ 25,711,870	$ 40,996,847	$	$ 66,708,717
Warrant liability			716,786	716,786
Total liabilities at fair value	$	$	$ 716,786	$ 716,786

The above table excludes a certificate of deposit in the amount of $1,001,802 that the Company held as of December 31, 2013.

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	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
As of December 31, 2012:				
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

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, 2013 and 2012:

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
Change in fair value	(771,393)
Balance at December 31, 2013	$ 716,786

(g) LONG-LIVED ASSETS OTHER THAN GOODWILL

Long-lived assets other than goodwill consist of property and equipment. The aggregate balances for these long-lived assets were $445,655 and $434,168 as of December 31, 2013 and 2012, 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 the difference between the carrying value and fair value of the asset. The Company did not recognize any impairment charges for the years ended December 31, 2013, 2012 or 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

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The Company incurred debt issuance costs totaling $421,715 in connection with the Curis Royalty loan transaction, of which $215,000 related to expenses that the Company paid to third parties on behalf of BioPharma-II and the remaining $206,715 were incurred directly by the Company. The debt issuance costs incurred directly by the Company were capitalized as assets and will be amortized over the estimated term of the debt using the straight-line. 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 the debt issuance costs, as well as the period over which these costs will be amortized (see Note 7). As of December 31, 2013 and 2012, the Company had recorded short-term debt issuance costs of $51,441 and $49,019, respectively, and long-term debt issuance costs of $101,055 and $154,868, respectively. These costs are reported within the prepaid expenses and other current assets and other assets line items, respectively, in the Company s Consolidated Balance Sheet at December 31, 2013 and 2012.

(h) GOODWILL

As of December 31, 2013 and 2012, 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 2013, 2012 and 2011, 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, 2013, 2012 and 2011.

(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.

The Company s 2000 Stock Incentive Plan and the Amended and Restated 2010 Plan generally allow participants to purchase common stock upon the exercise of a stock option by delivery of shares of Company common stock held directly by the participant, with such shares of common stock valued at the closing price on the Nasdaq Global Market, or NASDAQ, on the date of exercise. During the year ended December 31, 2013, certain executive officers and a director exercised stock options by remitting shares of Curis common stock then held by the respective person. The Company accounted for the value of the common stock remitted to the Company in satisfaction of the exercise price as treasury stock under the cost method. These option holders remitted an aggregate of 175,139 shares during the year ended December 31, 2013 with an aggregate value equal to $632,755.

(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, 2013, 2012 and 2011 consisted of the following:

	As of December 31,		
	2013	2012	2011
Stock options outstanding	10,077,805	10,437,761	11,094,241
Warrants outstanding	1,373,517	1,373,517	1,610,818
Total antidilutive securities	11,451,322	11,811,278	12,705,059

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(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 8(a)).

(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, 2013, represents amounts due from collaborators, primarily for royalties earned on sales of Erivedge by Genentech and Roche.

The Company relies on third parties to supply certain raw materials necessary to produce its drug candidates, including CUDC-907 and CUDC-427, 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.

(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 2013, the FASB issued an accounting standards update clarifying the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The updated guidance requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carryforward when settlement of the liability for an unrecognized tax benefit in this manner is available. The update is effective prospectively for reporting periods beginning after December 15, 2013, and early adoption and retrospective adoption are permitted. The adoption of this guidance is not expected to have an impact on the Company s consolidated financial statements.

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(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. Genentech is currently conducting a phase II clinical trial with Erivedge in less severe 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 other third-party investigators.

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 $56,000,000 as of December 31, 2013.

In addition to these payments, the Company s wholly-owned subsidiary, Curis Royalty, is entitled to a royalty on net sales of Erivedge that ranges from 5% to high single digits based upon global Erivedge sales by Roche and Genentech, subject to reduction under specified circumstances. Future royalty payments related to Erivedge will service the outstanding debt and accrued interest to BioPharma-II, up to the quarterly caps for 2014 and 2015, and until the debt is fully repaid thereafter (see Note 7).

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 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 account. The Company determined that the deliverables, specifically, the license, research and development services and steering committee participation, represented a single unit of account 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. 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 and consideration received after this date is recognized in the Company s financial statements in the period in which it was earned.

The Company received payments from Genentech totaling $10,000,000 during the year ended December 31, 2013 and $14,000,000 during each of the years ended December 31, 2012 and 2011, respectively, for the achievement of certain clinical and regulatory 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, 2013, 2012 and 2011, respectively.

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

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December 31, 2013, the Company has incurred aggregate research and development expenses over the term of this collaboration of $4,214,000 in connection with its receipt of cash payments from Genentech for research, development and regulatory objectives achieved related to such university licensing agreements. In 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 and its application to the Therapeutic Goods Administration, or TGA, for marketing registration of Erivedge in Australia based on the $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 years ended December 31, 2013 and 2011, the Company recorded research and development expenses of $500,000 and $700,000, respectively, representing 5% of the total cash payments received during each year.

In addition, the Company recognized $3,942,136 and $1,529,644 in royalty revenue from Genentech s net sales of Erivedge during the year ended December 31, 2013 and 2012, respectively. The Company also recorded cost of royalty revenues within the costs and expenses section of its Consolidated Statements of Operations and Comprehensive Loss of $197,796 and $176,482, respectively, during these same periods, which represents 5% of the royalties earned by Curis Royalty with respect to Erivedge that the Company is obligated to pay to university licensors. In addition to the 5% obligation, the Company made a one-time cash payment of $100,000 paid to one university licensor upon the first commercial sale of Erivedge during the year ended December 31, 2012.

During the years ended December 31, 2013, 2012 and 2011, the Company also recorded Research and development revenue of $291,448, $363,000 and $388,000, 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 $1,455,000, comprised primarily of Erivedge royalties earned in the fourth quarter of 2013, and $622,000, as of December 31, 2013 and 2012, 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 CUDC-427.

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

Under the terms of the agreement, the Company 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 is 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 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 and Comprehensive Loss.

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. Since the inception of the agreement, the Company has received $1,650,000 from LLS related to milestones achieved under this agreement. Additional milestone payments may be earned assuming CUDC-907 continues to progress through the phase I clinical trial.

Under certain conditions associated with the Company s successful partnering and/or commercialization of CUDC-907 in the specified indications, the Company may be obligated to make payments, including royalties, to LLS of up to $10,000,000. This obligation is capped at 2.5 times the amount the Company receives from LLS, and, as of December 31, 2013, the maximum obligation, assuming that CUDC-907 successfully progresses through future clinical trials, would be $4,125,000. 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, 2013 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, 2013 as this program remains in the very early stages of clinical development.

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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 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, 2013.

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, which represent a single unit of account.

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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 and 2013 under the LLS agreement were substantive and recorded the related revenue totaling $650,000 and $1,000,000 in the years ended December 31, 2013 and 2012, respectively.

(4) STOCK PLANS AND STOCK BASED COMPENSATION

As of December 31, 2013, the Company had two shareholder-approved, share-based compensation plans: (i) the Amended and Restated 2010 Stock Incentive Plan, or the Amended and Restated 2010 Plan, adopted by the Board of Directors in March 2013 and approved by shareholders in May 2013 and (ii) the 2010 Employee Stock Purchase Plan, or the ESPP, adopted by the Board of Directors in April 2010 and approved by shareholders in June 2010. 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.

The Amended and Restated 2010 Stock Incentive Plan

The Amended and Restated 2010 Plan 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 9,000,000 shares of its common stock pursuant to awards granted under the Amended and Restated 2010 Plan. Options become exercisable as determined by the Board of Directors and expire up to 10 years from the date of grant. The Amended and Restated 2010 Plan uses a fungible share concept under which each share of stock subject to awards granted as options and stock appreciation rights (SARs), 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 1.3 shares per share under the award to be removed from the available share pool. As of December 31, 2013, 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, 2013, 3,647,503 shares remained available for grant under the Amended and Restated 2010 Plan.

During the year ended December 31, 2013, the Company s board of directors granted options to purchase 2,076,000 shares of the Company s common stock to officers and employees of the Company under the Amended and Restated 2010 Plan. These options vest over a four-year period.

During the year ended December 31, 2013, the Company s board of directors also granted options to its non-employee directors to purchase 260,000 shares of common stock under the Amended and Restated 2010 Plan. Of these, options to purchase 235,000 shares of common stock will vest monthly over a one-year period and options to purchase 25,000 shares of common stock will vest over a four-year period.

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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:

	For the Year Ended December 31,		
	2013	2012	2011
Expected term (years) Employees	6.0	6.0	6.0
Expected term (years) Officers and Directors	7.0	6.0	6.0
Risk-free interest rate	1.0-2.1%	1.0-1.2%	1.2-2.5%
Expected volatility	70-72%	74-76%	73-76%
Expected dividend yield	None	None	None

The expected volatility is based on the annualized daily historical volatility of the Company s stock price for a time period consistent with the expected term of each grant. Management believes that the historical volatility of the Company s stock price best represents the 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 has not historically paid cash dividends, and does not expect to pay cash dividends in the foreseeable future.

The stock price volatility and expected terms utilized in the calculation involve management s best estimates at that time, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. GAAP also requires that the Company recognize compensation expense for only the portion of options that are expected to vest. Therefore, management calculated an estimated annual pre-vesting forfeiture rate that is derived from historical employee termination behavior since the inception of the Company, as adjusted. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods.

At December 31, 2013, the aggregate intrinsic value of employee options outstanding was $5,979,000, of which $5,831,000 related to exercisable options, and the weighted average remaining contractual life of vested stock options was 4.46 years. The weighted average grant-date fair values of stock options granted during the years ended December 31, 2013, 2012 and 2011 were $2.27, $2.99 and $1.72 per share of common stock underlying such stock options, respectively. As of December 31, 2013, there was approximately $4,987,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding under the Company s 2000 Stock Incentive Plan and Amended and Restated 2010 Plan that is expected to be recognized as expense over a weighted average period of 2.8 years. The intrinsic value of employee stock options exercised during the years ended December 31, 2013, 2012 and 2011 were $2,091,000, $6,415,000 and $2,129,000, respectively. The total fair value of vested stock options for the years ended December 31, 2013, 2012 and 2011 were $2,716,000, $2,525,000 and $1,504,000, respectively.

Non-Employee Grants

Pursuant to the Company s stock plans, the Company has periodically granted stock options and unrestricted stock awards to consultants for services at the closing market price of the Company s common stock on NASDAQ on the grant date. During the year ended December 31, 2013, the Company issued options to purchase a total of 525,000 shares of common stock to consultants. These options were issued pursuant to the Amended and Restated 2010 Plan at exercise prices equal to the closing market price of the Company s common stock on NASDAQ on the grant date. Should the Company terminate any of its consulting agreements, the unvested options underlying the agreements would also be cancelled. Unvested non-employee options are marked-to-market, which means that as

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the Company s stock price fluctuates, the related expense either increases or decreases. The Company recognized expense of $351,089, $355,222 and $130,281 related to non-employee stock options and stock awards for the years ended December 31, 2013, 2012 and 2011, respectively.

A summary of stock option activity under the Amended and Restated 2010 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, 2012 (8,134,191 exercisable at weighted average price of $2.30 per share)	10,437,761	$ 2.59
Granted	2,861,000	3.44
Exercised	(2,118,953)	2.12
Cancelled	(1,102,003)	3.90
Outstanding, December 31, 2013 (6,884,869 exercisable at weighted average price of $2.44 per share)	10,077,805	$ 2.79
Vested and unvested expected to vest	9,920,751	$ 2.78

2010 Employee Stock Purchase Plan

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, 2013, 268,331 shares were issued under the ESPP, of which 47,215 were issued during 2013. As of December 31, 2013, there were 278,884 shares available for future purchase under the ESPP.

For the years ended December 31, 2013, 2012 and 2011, 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,		
	2013	2012	2011
Compensation expense recognized under ESPP	$ 40,008	$ 72,833	$ 94,529
Expected term	6 months	6 months	6 months
Risk-free interest rate	0.08-0.1%	0.05-0.15%	0.1-0.2%
Volatility	42-66%	42-75%	75-85%
Dividends	None	None	None

Stock-based compensation for employee and director stock option grants for the years ended December 31, 2013, 2012 and 2011 of $2,651,152, $3,268,689 and $1,641,830, respectively, was calculated using the above valuation models and has been included in the Company s results of operations.

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Total Stock-Based Compensation Expense

For the years ended December 31, 2013, 2012 and 2011, 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,		
	2013	2012	2011
Research and development expenses	$ 879,052	$ 1,075,134	$ 723,634
General and administrative expenses	2,123,189	2,548,777	1,048,477
Total stock-based compensation expense	$ 3,002,241	$ 3,623,911	$ 1,772,111

No income tax benefits have been recorded for the years ended December 31, 2013, 2012 or 2011, 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 10).

(5) PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	December 31,	
	2013	2012
Laboratory equipment, computers and software	$ 1,941,588	$ 2,167,794
Leasehold improvements	62,621	62,621
Office furniture and equipment	354,875	304,590
	2,359,084	2,535,005
Less Accumulated depreciation and amortization	(1,913,429)	(2,100,837)
Total	$ 445,655	$ 434,168

The Company recorded depreciation and amortization expense of $141,522, $126,537 and $107,396 for the years ended December 31, 2013, 2012 and 2011, respectively.

During the years ended December 31, 2013, 2012 and 2011, the Company identified certain of its fully depreciated assets no longer being used. As a result, the Company wrote off gross assets and related accumulated depreciation, totaling $329,000 for the year ended December 31, 2013 and $418,000 for each of the years ended December 31, 2012 and 2011, respectively.

(6) ACCRUED LIABILITIES

Accrued liabilities consist of the following:

	December 31,	
	2013	2012
Accrued compensation	$ 1,267,954	$ 999,038
Professional fees	166,200	127,500
Accrued interest on debt (see Note 7)	298,935	204,167

Other	178,390	143,851
Total	$ 1,911,479	$ 1,474,556

(7) DEBT

In December 2012, Curis wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan at an annual interest rate of 12.25% pursuant to a credit agreement between Curis Royalty and BioPharma-II.

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In connection with the loan, Curis transferred to Curis Royalty its right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that it may receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to Curis. Under the terms of the loan, quarterly royalty payments received by Curis Royalty from Genentech will first be applied to pay (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis royalty obligations to academic institutions, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by Curis enforcing its right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject to caps of $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 the remaining royalty amounts above the caps, if any, and Curis remains entitled to receive any contingent payments upon achievement of clinical development objectives. Curis Royalty retains its right to royalty payments related to sales of Erivedge following repayment of the loan.

The final maturity date of the loan will be the earlier of the date when the principal is paid in full 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.

Curis Royalty made quarterly interest payments under the loan agreement totaling $2,928,068 during the year ended December 31, 2013. Each of the quarterly payments represented only a portion of the interest accrued through each payment date until the fourth quarter of 2013, when such payment exceeded the interest accrued. As a result, the shortfall in the accrued but unpaid interest totaling $753,639 was added to the principal portion of the loan, of which $39,671 of the capitalized interest was repaid during the year ended December 31, 2013. As of December 31, 2013, the Company recorded short- and long-term debt of $2,610,174 and $27,945,186, respectively (net of unamortized issuance costs of $53,503 and $105,105, respectively), and at December 31, 2012 recorded long-term debt of $29,838,925 (net of unamortized issuance costs of $161,075), related to the loan, with such amounts recorded within the Company s Consolidated Balance Sheets. In addition, the Company recorded related accrued interest on the debt of $298,935 and $204,167 as of December 31, 2013 and 2012, respectively, with such amounts included in the Company s accrued liabilities section of its Consolidated Balance Sheets. Because the repayment of the term loan is contingent upon the level of Erivedge royalties received, 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, Curis management estimates that the loan will be repaid in the first half of 2017. However, the actual repayment period could vary materially from the Company s estimate to the extent that royalty payments it receives are lower than the Company s current estimates, which could arise due to factors beyond the Company s control, such as due to competitive factors, decreased market acceptance or a failure by Genentech and/or Roche to obtain required regulatory approvals.

At December 31, 2013, the fair value of the principal portion of the debt is estimated as $30,610,000. Due to the assumptions required in estimating future Erivedge royalties, the expected repayment period and weighting of various royalty projection scenarios, determining the fair value of the debt required application of Level 3 inputs.

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The Company incurred debt issuance costs totaling $421,715 in connection with this loan 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 debt issuance costs incurred directly by the Company were capitalized as assets and those costs paid on behalf of BioPharma-II have been netted against the debt and accrued interest in the Company s Condensed Consolidated Balance Sheets as of December 31, 2013 and 2012 as detailed in the following table:

	As of December 31,	
	2013	2012
Other current assets	$ 51,441	$ 49,019
Other assets	101,055	154,868
Total debt issuance costs	152,496	203,887
Accrued liabilities, net against accrued interest		(50,984)
Debt, current	2,663,677	
Debt issue costs, current	(53,503)	
Debt, current portion net of issuance costs	$ 2,610,174	$
Debt, long-term	28,050,291	30,000,000
Debt issue costs, long-term	(105,105)	(161,075)
Debt, net of current portion and issuance costs	$ 27,945,186	$ 29,838,925

All issuance costs are being amortized over the estimated term of the debt using the straight-line method which approximates the effective interest method. For the year ended December 31, 2013, the Company recognized interest expense related to the loan with BioPharma-II of $3,841,646 within the Company s Consolidated Statement of Operations, comprised of interest accrued on the outstanding principal of the loan of $3,736,804 and amortization of debt issuance costs of $104,842. For the year ended December 31, 2012, the Company recognized interest expense related to the loan with BioPharma-II of $204,167 within the Company s Consolidated Statement of Operations. 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 short- and long-term classification of these costs, as well as the period over which these costs will be amortized.

Future payments of principal on the loan will require application of these same assumptions and will be used to estimate short- and long-term classification of the debt within the Company s consolidated balance sheets. At December 31, 2013, the Company estimates that its future payments of principal on the loan are as follows:

	Principal
2014	$ 2,663,677
2015	7,504,387
2016	14,076,158
2017	6,469,746
Thereafter	
Total payments	30,713,968
Less current portion, gross	(2,663,677)
Total long-term debt obligations, gross	$ 28,050,291

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(8) COMMITMENTS

(a) OPERATING LEASES

The Company is party to a lease agreement with the Trustees of Lexington Office Realty Trust pursuant to which the Company leases 24,529 square feet of property that is used for office, research and laboratory space located at 4 Maguire Road in Lexington, Massachusetts.

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. The original deposit has been reduced since the inception of the lease, to $194,282 during 2012 and to $180,364 during 2013, and will continue to be reduced up to an additional $13,877 per year in 2014 and 2015, respectively, in accordance with the terms of the lease. These amounts have been classified as the restricted investments in the Company s Consolidated Balance Sheet as of December 31, 2013 and 2012.

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:

Year Ending December 31,	
2014	$ 627,000
2015	651,000
2016	676,000
2017	700,000
2018	59,000
Thereafter	
Total minimum payments	$ 2,713,000

Rent expense for all operating leases was $614,000 for each of the years ended December 31, 2013, 2012 and 2011, 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

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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, 2013, 2012 and 2011, of $500,000, $2,114,000, and $908,000, respectively. For the years ended December 31, 2013 and 2012, the Company also recognized $197,796 and $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)).

(9) COMMON STOCK AND WARRANT LIABILITY

(a) 2013 Sales Agreement with Cowen

On July 3, 2013, the Company entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which the Company may sell from time to time up to $30,000,000 of its common stock through an at-the-market , or ATM, equity offering program under which Cowen will act as sales agent. Subject to the terms and conditions of the sales agreement, Cowen may sell the common stock by methods deemed to be an at-the-market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on NASDAQ, on any other existing trading market for the common stock or to or through a market maker other than on an exchange. In addition, with the Company s prior written approval, Cowen may also sell the common stock by any other method permitted by law, including in negotiated transactions. Cowen will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of NASDAQ to sell on the Company s behalf all of the shares requested to be sold by the Company. The Company has no obligation to sell any of the common stock under the sales agreement. Either the Company or Cowen may at any time suspend solicitations and offers under the sales agreement upon notice to the other party. The sales agreement may be terminated at any time by either the Company or Cowen upon written notice to the other party as specified in the sales agreement. The aggregate compensation payable to Cowen shall be 3% of the gross sales price of the common stock sold by Cowen pursuant to the sales agreement. In addition, the Company reimbursed $34,268 of Cowen s expenses of Cowen in connection with the offering. Each party has agreed in the sales agreement to provide indemnification and contribution against certain liabilities, including liabilities under the Securities Act, subject to the terms of the sales agreement. Common stock will be issued pursuant to the Company s currently-effective shelf registration statement on Form S-3. During the year ended December 31, 2013, the Company sold 3,850,206 shares of common stock under the sales agreement resulting in gross proceeds of $16,887,036. Total offering expenses incurred, including Cowen s commission, related to the sales agreement through December 31, 2013 were $641,052, which offset the gross proceeds.

(b) 2011 At Market Issuance Sales Agreement with MLV

On June 13, 2011, the Company entered into an ATM agreement with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which the Company could issue and sell from time to time up to $20,000,000 of its common stock through MLV in at-the-market and other specified forms of sale. The ATM Agreement terminated in June 2013 in accordance with the terms of the agreement

During the years ended December 31, 2012 and 2011, the Company 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.

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(c) 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, 2013, warrants to purchase 238,805 shares of the Company s common stock have been exercised, resulting in outstanding warrants to purchase an aggregate of 1,373,517 shares of common stock.

The warrants have an initial exercise price of $3.55 per share and a five-year term. The warrants contain anti-dilution 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 the Company at prices below $3.55 per share. 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, 2013 and 2012. 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:

	As of December 31,		
	2013	**2012**	**2011**
Fair value of the warrants	$ 716,786	$ 1,488,179	$ 4,361,168
Expected term	1.1 years	2.1 years	3 years
Risk-free interest rate	0.16%	0.27%	0.4%
Volatility	65%	58%	78%
Dividends	None	None	None

The Company recorded other expense of $2,756,426 for the year ended December 31, 2011 and other income of $771,393 and $2,257,130 for the years ended December 31, 2013 and 2012, 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.

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(10) INCOME TAXES

For the years ended December 31, 2013, 2012 and 2011, the Company did not record any federal or state income tax expense given its continued operating losses.

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,		
	2013	2012	2011
Statutory federal income tax rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit	5.2%	5.8%	5.1%
Research and development tax credits	8.5%	0.8%	5.4%
Deferred compensation	0.8%	2.1%	(0.4%)
Interest expense	(2.5%)	%	%
Fair value of warrants	2.1%	%	%
NOL expirations	(5.2%)	(36.0%)	(17.3%)
Other	0.1%	(1.7%)	(1.9%)
Net (decrease) increase in valuation allowance	(43.0%)	(5.0%)	(24.9%)
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, 2013 and 2012, respectively are as follows:

	December 31,	
	2013	2012
Deferred Tax Assets:		
Net operating loss carryforwards	$ 72,446,000	$ 67,737,000
Research and development tax credit carryforwards	11,588,000	10,538,000
Depreciation and amortization	3,891,000	490,000
Capitalized research and development expenditures	23,711,000	27,269,000
Impairment of investments	120,000	64,000
Stock options	2,723,000	2,809,000
Accrued expenses and other	118,000	707,000
Deferred interest expense	307,000	
Total Gross Deferred Tax Asset	114,904,000	109,614,000
Valuation Allowance	(114,904,000)	(109,614,000)
Net Deferred Tax Asset	$	$

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The classification of the above deferred tax assets is as follows:

	December 31,	
	2013	2012
Deferred Tax Assets:		
Current deferred tax assets	$ 35,000	$ 42,000
Non-current deferred tax assets	114,869,000	109,572,000
Valuation Allowance	(114,904,000)	(109,614,000)
Net Deferred Tax Asset	$	$

As of December 31, 2013, the Company had federal and state net operating losses, or NOLs, of $206,688,000 and $43,072,000, respectively, and federal and state research and experimentation credit carryforwards of approximately $9,320,000 and $3,436,000, respectively, which will expire at various dates starting in 2018 through 2033. The Company had $10,307,000 of Massachusetts net operating losses generated in 2008 that expired in 2013. As required by U.S. 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 $114,904,000 has been established at December 31, 2013. 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, 2013 and 2012, 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 2013 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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(11) RELATED PARTY TRANSACTIONS

(a) Agreement with Director

On March 7, 2013, the Company s Board of Directors elected Kenneth J. Pienta, M.D., to serve as a class I director until the 2015 Annual Meeting of Stockholders and thereafter until his successor is duly elected and qualified. Dr. Pienta has served as a member of the Company s Scientific Advisory Board since September 2006 and as its Chairman since June 2007, pursuant to the terms of a Scientific Advisory Board Agreement, or the SAB agreement, effective September 13, 2006, as amended from time to time, by and between Dr. Pienta and the Company. Pursuant to the SAB agreement, Dr. Pienta receives compensation in the amount of $50,000 per year, payable in equal quarterly installments. In addition, pursuant to the terms of a consulting agreement dated March 1, 2012, as amended from time to time, by and between the Company and Dr. Pienta, Dr. Pienta served as a consultant to the Company in the areas of corporate strategy and business development. The Company and Dr. Pienta terminated the consulting agreement in connection with his election as a member of the Board of Directors in March 2013. Pursuant to the terms of the SAB agreement and the consulting agreement, the Company paid cash consideration of $72,258, $190,000 and $193,750 during the years ended December 31, 2013, 2012 and 2011, respectively, as it relates to services provided by Dr. Pienta. In addition, the Company s board of directors granted two options to purchase an aggregate of 125,000 shares of the Company s common stock to Dr. Pienta in his role on the SAB. 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.

(b) License Agreement with Former Officer

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. 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. GBMT has assumed all future development responsibility and will 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, 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 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

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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. No such expenses were incurred during the year ended December 31, 2013.

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 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.

(12) RETIREMENT SAVINGS PLAN

The Company has a 401(k) retirement savings plan covering substantially all of the Company s employees. Matching Company cash contributions are at the discretion of the Board of Directors. For the years ended December 31, 2013, 2012 and 2011, the Board of Directors authorized matching contributions of $145,000, $153,000 and $145,000, respectively.

(13) SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following are selected quarterly financial data for the years ended December 31, 2013 and 2012:

	Quarter Ended			
	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
Revenues	$ 871,435	$ 5,404,377	$ 7,202,083	$ 1,524,137
(Loss) income from operations	(4,357,364)	(706,196)	130,368	(4,483,217)
Net loss	(4,962,294)	(1,293,848)	(1,867,838)	(4,198,032)
Net loss per common share (basic and diluted)	$ (0.06)	$ (0.02)	$ (0.02)	$ (0.05)
Weighted average common shares (basic and diluted)	80,096,650	81,128,475	82,456,708	85,741,278

	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

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.

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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, 2013. 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, 2013, 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 1992 *Internal Control Integrated Framework*.

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, 2013 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 GOVERANCE

Information concerning directors that is required by this Item 10 will be set forth in our proxy statement for our 2014 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 will be set forth in our proxy statement for our 2014 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 will be set forth in our 2014 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 will be set forth in our 2014 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 will be set forth in our proxy statement for our 2014 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 will be set forth in our proxy statement for our 2014 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.*

(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.

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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, 2014

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.

Signature	Title	Date
/s/ DANIEL R. PASSERI **Daniel R. Passeri**	Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2014
/s/ MICHAEL P. GRAY **Michael P. Gray**	Chief Financial and Business Officer (Principal Financial and Accounting Officer)	March 13, 2014
/s/ JAMES R. MCNAB, JR. **James R. McNab, Jr.**	Chairman of the Board of Directors	March 13, 2014
/s/ MARTYN D. GREENACRE **Martyn D. Greenacre**	Director	March 13, 2014
/s/ KENNETH I. KAITIN **Kenneth I. Kaitin**	Director	March 13, 2014
/s/ ROBERT MARTELL **Robert Martell**	Director	March 13, 2014
/s/ KENNETH PIENTA **Kenneth Pienta**	Director	March 13, 2014
/s/ MARC RUBIN **Marc Rubin**	Director	March 13, 2014

/s/ James R. Tobin	Director	March 13, 2014

James R. Tobin

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EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
	Articles of Incorporation and By-laws				
3.1	Restated Certificate of Incorporation of Curis, Inc.	S-4/A (333-32446)	06/19/00	3.3	
3.2	Amended Certificate of Incorporation of Curis, Inc.	8-K	06/03/13	3.1	
3.3	Certificate of Designations of Curis, Inc.	S-3 (333-50906)	08/10/01	3.2	
3.4	Amended and Restated By-laws of Curis, Inc.	S-1 (333-50906)	11/29/00	3.2	
3.5	Amendment to Amended and Restated By-laws of Curis, Inc.	8-K	09/24/07	3.1	
	Instruments defining the rights of security holders, including indentures				
4.1	Form of Curis Common Stock Certificate	10-K	03/01/04	4.1	
	Material contracts Management Contracts and Compensatory Plans				
#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	

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Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
#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	
#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	Employment Agreement, dated February 19, 2013, by and between Curis and Ali Fattaey, Ph.D.	8-K	02/22/13	10.1	
#10.15	Employment Agreement, dated August 28, 2013, by and between Curis and Jaye Viner, M.D.	10-Q	11/12/13	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	Form of Indemnification Agreement, between Curis, Inc. and each member of the Board of Directors	10-K	03/08/11	10.23	
#10.18	Scientific Advisory and Consulting Agreement dated as of September 13, 2006, as amended from time to time, between Curis, Inc. and Kenneth J. Pienta, M.D.	8-K	03/11/13	10.1	
#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	

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Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
#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	
#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	
#10.30	Curis Amended and Restated 2010 Stock Incentive Plan	Def 14A	04/16/13	Exhibit A	
	Material contracts Leases				
10.31	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	
	Material contracts Financing Agreements				
10.32	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.	10-K	3/13/2013	10.31	
10.33	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.	10-K	3/13/2013	10.32	
10.34	Purchase and Sale Agreement, dated as of December 11, 2012 between Curis and Curis Royalty	10-K	3/13/2013	10.33	

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Exhibit No.	Description	Incorporated by Reference Form	SEC Filing Date	Exhibit Number	Filed with this 10-K
10.35	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	10-K	3/13/2013	10.34	
	Material contracts License and Collaboration Agreements				
10.36	Collaborative Research, Development and License Agreement, dated June 11, 2003, between Curis and Genentech, Inc.	10-Q	11/06/2012	10.1	
10.37	License Agreement, dated August 5, 2009, by and between the Company and Debiopharm S.A	10-Q	10/29/09	10.1	
10.38	Definitive Agreement, dated November 29, 2011, by and between Curis and The Leukemia and Lymphoma Society	10-K	3/13/2013	10.37	
10.39	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	
10.40	License Agreement, dated November 27, 2012, by and between Curis and Genentech, Inc.	10-K	3/13/2013	10.39	
	Material contracts Miscellaneous				
10.41	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	
10.42	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	
10.43	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	
10.44	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	
10.45	Sales Agreement, dated as of July 3, 2013, between Curis, Inc. and Cowen and Company, LLC	S-3	07/03/13	1.2	

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Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
	Code of Conduct				
14	Code of Business Conduct and Ethics	10-K	03/08/11	14	
	Additional Exhibits				
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				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

# 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.