

Curis is an oncology-focused drug development company seeking to develop and commercialize next generation targeted small molecule drug candidates for cancer treatment. Erivedge® is the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma and is being commercialized and developed by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech. Curis is also leveraging its experience in targeting signaling pathways to develop proprietary targeted cancer programs, including CUDC-427, a small molecule antagonist of IAP proteins, and CUDC-907, a dual PI3K and HDAC inhibitor.

#### Dear Curis Stockholders,

2012 was an important and productive year for Curis, placing the company in what we believe is the strongest position in our corporate history. Notable among the accomplishments of 2012 was the FDA's approval of our collaborator Genentech's NDA submission of a first-in-class Hedgehog pathway inhibitor, Erivedge®, for the treatment of adults suffering with advanced basal cell carcinoma, or BCC. In 2012, we also advanced our proprietary and novel dual targeted PI3K and HDAC inhibitor CUDC-907 and began treating patients with refractory or relapsed lymphomas or multiple myeloma in a Phase I study earlier this year. Furthermore, we substantially strengthened our capital resources and enhanced our pipeline by the completion of a \$30 million Erivedge-secured royalty financing transaction and the simultaneous acquisition from Genentech of the exclusive global rights to the Phase II-ready IAP inhibitor CUDC-427. We view these two transactions as core components to our overall strategy to build a leading oncology company seeking to develop breakthrough therapies for patients suffering from various forms of cancer. It is our intended plan to use the approximately \$59 million in 2012 year-end capital to progress the ongoing clinical development of CUDC-907, as well as to initiate a Phase II campaign for CUDC-427. Finally, our partner Debiopharm advanced HSP90 inhibitor Debio 0932 into a Phase Ib study as well as a Phase I/II clinical trial in patients with advanced lung cancer and also announced plans to expand development into renal cell carcinoma in 2013.

In addition to the advances of our clinical development programs, we substantially improved our balance sheet through the receipt of \$47 million in non-dilutive capital, comprised of \$30 million in non-recourse capital through our Erivedge royalty-secured financing transaction, \$16 million in milestone and royalty payments from Genentech related to regulatory milestones and commercialization of Erivedge and \$1 million from the Leukemia and Lymphoma Society (LLS) for the achievement of CUDC-907 development objectives. Due to the strengthening of our balance sheet, we currently expect our existing capital to provide the requisite funding for our planned operations into mid-2015. Importantly, this capital projection does not include four potential milestone payments that we are eligible to receive under our agreements with Genentech and Debiopharm during 2013 and 2014, the receipt of which would meaningfully extend the period in which we can fund our operations. In addition, the terms of our royalty financing agreement provide that our quarterly payment obligations are capped in 2013, 2014 and 2015, respectively. Royalties that we receive in excess of the quarterly caps, if any, revert to Curis and would be used as additional capital to fund our operations.

We believe that Curis represents a highly attractive investment opportunity within the biotechnology space, providing investors with significant upside potential from our proprietary clinical development programs, combined with the growing value prospects from our commercial asset in Erivedge<sup>®</sup>, as well as an additional partnered asset in Debio 0932. We view our ability to advance promising drug candidates further into clinical development as a critical next step to increasing the value of Curis and believe we are now well situated to focus upon the realization of that value.

The following summarizes the status of our key programs.

#### Erivedge®: Commercial-Stage Hedgehog Pathway Inhibitor

Erivedge® is the first and only FDA-approved medicine for patients suffering with advanced BCC and is also the first and only Hedgehog pathway inhibitor to reach commercialization. Prior to the approval of Erivedge®, no effective therapies were available for patients suffering with this debilitating and often life-threatening cancer. Erivedge is Curis' first FDA approved drug and represents a landmark event for the company, our stockholders and most importantly, for patients suffering from advanced BCC. In addition to the United States, Erivedge® has also been approved in Israel, Mexico, and South Korea. Erivedge® is currently under regulatory review for approval by European and Australian health authorities, among others, and we are eligible to receive further cash payments upon approval in each of the European and Australian territories. Approvals in additional markets would increase patient access to Erivedge® and increase the market size and value of this important breakthrough drug.

Genentech is also conducting a separate Phase II clinical trial of Erivedge® in patients with operable nodular BCC, which is a less severe form of the disease and accounts for a significant percentage of the over two million cases of BCC diagnosed annually in the United States. Genentech has advised us that further study and analysis of Erivedge® in operable BCC is ongoing and we currently anticipate that the study will be completed in the second half of 2013. We view positive data in this study as an important next step to realizing the full value and potential patient benefits for Erivedge® within the advanced BCC market.

#### CUDC-427: Phase II-Ready Antagonist of IAP Proteins

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. We incurred costs of \$9.5 million upon entry into this license agreement and Genentech will be entitled to receive milestone payments upon the first commercial sale of CUDC-427 in certain territories as well as tiered low-to-mid single digit royalties on net sales of CUDC-427.

IAP proteins are a family of functionally and structurally related proteins that promote cancer cell survival by inhibiting the process of programmed cell death, also known as apoptosis. The ability to escape apoptosis is a hallmark of cancer and the ability to inactivate the IAPs protecting cancer cells may provide significant benefits to cancer patients by enhancing the effectiveness of their current therapies. CUDC-427 is designed to counteract the effects of IAP proteins, thus shifting the balance away from cancer cell survival towards cancer cell death.

Prior to our acquiring the rights to CUDC-427, Genentech completed a dose escalation Phase I clinical trial of CUDC-427, previously named GDC-0917, in which 42 patients received daily oral doses of CUDC-427 for two weeks, followed by a one week rest period until disease progression or study discontinuation for any other reason. Genentech plans to present the full study results at the American Society of Clinical Oncology's meeting in June 2013.

#### CUDC-907: Phase I Dual PI3K and HDAC Inhibitor

In January 2013, we began treating relapsed or refractory lymphoma or multiple myeloma patients in a Phase I clinical study of CUDC-907. CUDC-907 is an orally-administered first-in-class small molecule drug candidate that has been designed as a dual inhibitor of PI3K and HDAC. We believe that the properties of CUDC-907 may provide significant advantages for competitive positioning and patient benefit. CUDC-907 is designed to inhibit the two PI3K isoforms primarily involved in cancer biology, namely alpha and delta, combined with an HDAC binding moiety with the intention of providing for suppression of tumor driving pathways as well as potential drug resistance mechanisms. Curis scientists have shown that synergistic effects of targeting PI3K and HDAC with CUDC-907 result in potent antitumor activity in multiple preclinical models of lymphoma, multiple myeloma, as well as in various solid tumor models.

The ongoing 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 at up to four study centers in the United States. We are hopeful that CUDC-907 will demonstrate an adequate safety profile and also provide effective clinical activity in this study population.

We entered into an agreement with the LLS in 2011 pursuant to which LLS agreed to fund approximately 50% of the direct costs of the development of CUDC-907, up to \$4 million, of which we have received \$1.1 million in funding to date. Provided that the Phase I study is successful, the agreement also provides for LLS to support Curis' subsequent Phase Ib or Phase IIa study in one or more specific indications as well as Curis' ongoing investigation of biomarkers for CUDC-907 in these diseases.

In addition to this study, we also anticipate that we will begin an additional clinical study of this molecule in solid tumor cancers later in 2013.



VOTE BY INTERNET - www.proxyvote.com
Use the Internet to transmit your voting instructions and for electronic delivery of information up until 11:59 P.M. Eastern Time on May 29, 2013. Have your proxy card in hand when you access the web site and follow the instructions to obtain your records and to create an electronic voting instruction form.

ELECTRONIC DELIVERY OF FUTURE PROXY MATERIALS
If you would like to reduce the costs incurred by our company in mailing proxy
materials, you can consent to receiving all future proxy statements, proxy cards and annual reports electronically via e-mail or the Internet. To sign up for electronic delivery, please follow the instructions above to vote using the Internet and, when prompted, indicate that you agree to receive or access proxy materials electronically in future years.

VOTE BY PHONE - 1-800-690-6903

Use any touch-tone telephone to transmit your voting instructions up until 11:59 P.M. Eastern Time on May 29, 2013. Have your proxy card in hand when you call and then follow the instructions.

Mark, sign and date your proxy card and return it in the postage-paid envelope we have provided or return it to Vote Processing, c/o Broadridge, 51 Mercedes Way, Edgewood, NY 11717.

Date

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Signature (Joint Owners)

Signature [PLEASE SIGN WITHIN BOX]

#### CURIS, INC.

# PROXY FOR THE ANNUAL MEETING OF STOCKHOLDERS To be held May 30, 2013 THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS OF THE COMPANY AND SHOULD BE RETURNED AS SOON AS POSSIBLE

Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting: The Notice & Proxy Statement, Form 10-K and Annual Report is/are available at <a href="https://www.proxyvote.com">www.proxyvote.com</a>.

# CURIS, INC. Annual Meeting of Stockholders May 30, 2013 10:00 AM This proxy is solicited by the Board of Directors

The undersigned, having received notice of the Annual Meeting of Stockholders and the Board of Directors' proxy statement therefore, and revoking all prior proxies, hereby appoint(s)

Daniel R. Passeri and Michael P. Gray, and each of them, attorneys or attorney of the undersigned (with full power of substitution in them and each of them) for and in the name(s) of the undersigned to attend the Annual Meeting of Stockholders of Curis, Inc. (the "Company") to be held on Thursday, May 30, 2013, at 10:00 a.m. local time, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109, and any adjournments thereof, and there to vote and act upon the following matters proposed by the Company in respect of all shares of stock of the Company which the undersigned may be entitled to vote or act upon, with all the powers the undersigned would possess if personally present. None of the following proposals is conditioned upon the approval of any other proposal. In their discretion, the proxy holders are authorized to vote upon such other matters as may properly come before the meeting or any adjournments thereof. The shares represented by this proxy will be voted as directed by the undersigned. If no direction is given with respect to any election to office or proposal, this proxy will be voted as recommended by the Board of Directors. Attendance of the undersigned at the meeting or at any adjournment thereof will not be deemed to revoke this proxy unless the undersigned shall revoke this proxy in writing. WHETHER OR NOT YOU PLAN TO ATTEND THE ANNUAL MEETING, YOU ARE URGED TO COMPLETE, DATE AND SIGN THIS PROXY AND RETURN IT IN THE ACCOMPANYING ENVELOPE. A VOTE "FOR" EACH OF THE DIRECTOR NOMINEES AND A VOTE "FOR" PROPOSALS 2, 3 AND 4 ARE RECOMMENDED BY THE BOARD OF DIRECTORS. IN THEIR DISCRETION, THE PROXIES ARE AUTHORIZED TO VOTE UPON SUCH OTHER BUSINESS AS MAY PROPERLY COME BEFORE THE ANNUAL MEETING AND ANY ADJOURNMENT THEREOF.

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(If you noted any Address Changes and/or Comments above, please mark corresponding box on the reverse side.)

Continued and to be signed on reverse side

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# \*\*\* Exercise Your Right to Vote \*\*\* Important Notice Regarding the Availability of Proxy Materials for the Shareholder Meeting to Be Held on May 30, 2013

CURIS, INC.



## **Meeting Information**

Meeting Type: Annual Meeting For holders as of: April 01, 2013

**Date:** May 30, 2013 T

Time: 10:00 AM EDT

Location: Wilmer Cutler Pickering Hale

and Dorr, LLP 60 State Street Boston, MA 02109

You are receiving this communication because you hold shares in the above named company.

This is not a ballot. You cannot use this notice to vote these shares. This communication presents only an overview of the more complete proxy materials that are available to you on the Internet. You may view the proxy materials online at www.proxyvote.com or easily request a paper copy (see reverse side).

We encourage you to access and review all of the important information contained in the proxy materials before voting.

See the reverse side of this notice to obtain proxy materials and voting instructions.

# Before You Vote —

How to Access the Proxy Materials

#### Proxy Materials Available to VIEW or RECEIVE:

1. Notice & Proxy Statement 2. Form 10-K and Annual Report

#### How to View Online:

Have the information that is printed in the box marked by the arrow  $\rightarrow$  XXXX XXXX XXXX (located on the following page) and visit: www.proxyvote.com.

### How to Request and Receive a PAPER or E-MAIL Copy:

If you want to receive a paper or e-mail copy of these documents, you must request one. There is NO charge for requesting a copy. Please choose one of the following methods to make your request:

1) BY INTERNET:

www.proxyvote.com

2) BYTELEPHONE: 1-800-579-1639

3) BY E-MAIL\*:

sendmaterial@proxyvote.com

\* If requesting materials by e-mail, please send a blank e-mail with the information that is printed in the box marked by the arrow (located on the following page) in the subject line.

Requests, instructions and other inquiries sent to this e-mail address will NOT be forwarded to your investment advisor. Please make the request as instructed above on or before May 16, 2013 to facilitate timely delivery.

# — How To Vote —

# Please Choose One of the Following Voting Methods

**Vote In Person:** Many shareholder meetings have attendance requirements including, but not limited to, the possession of an attendance ticket issued by the entity holding the meeting. Please check the meeting materials for any special requirements for meeting attendance. At the meeting, you will need to request a ballot to vote these shares.

**Vote By Internet:** To vote now by Internet, go to www.proxyvote.com. Have the information that is printed in the box marked by the arrow  $\rightarrow$  XXXX XXXX XXXX available and follow the instructions.

Vote By Mail: You can vote by mail by requesting a paper copy of the materials, which will include a proxy card.

#### Voting items

The Board of Directors recommends that you vote FOR the following:

1. Election of Directors Nominees

01 Robert E. Martell

02 Daniel R. Passeri

03 Marc Rubin

The Board of Directors recommends you vote FOR the following proposals:

- 2 To approve the Amended and Restated 2010 Stock Incentive Plan
- 3 To approve an Amendment to our Restated Certificate of Incorporation
- 4 To ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the current fiscal year

NOTE: Such other business as may properly come before the meeting or any adjournment thereof.

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#### CURIS, INC.

# NOTICE OF ANNUAL MEETING OF STOCKHOLDERS TO BE HELD MAY 30, 2013

NOTICE IS HEREBY GIVEN that the annual meeting of stockholders of Curis, Inc. will be held on May 30, 2013 at 10:00 a.m. at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109 for the purpose of considering and voting upon the following matters:

- 1. To elect three Class II directors, each for a term of three years;
- 2. To approve our Amended and Restated 2010 Stock Incentive Plan;
- 3. To approve an Amendment to our Restated Certificate of Incorporation; and
- To ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the current fiscal year ending December 31, 2013.

The stockholders will also act on any other business that may properly come before the meeting or any adjournment thereof.

The board of directors has fixed the close of business on April 1, 2013 as the record date for the determination of stockholders entitled to notice of and to vote at the meeting and at any adjournments thereof. Your vote is very important to us. Whether or not you plan to attend the annual meeting in person, your shares should be represented and voted.

In accordance with rules adopted by the Securities and Exchange Commission, we are now furnishing proxy materials to many of our stockholders on the Internet, rather than mailing paper copies of the materials to each stockholder. If you received only a Notice of Internet Availability of Proxy Materials, or Notice, by mail or e-mail, you will not receive a paper copy of the proxy materials unless you request one. Instead, the Notice will provide you with instructions on how to access and view the proxy materials on the Internet. The Notice will also instruct you as to how you may access your proxy card to vote over the Internet or by telephone. If you received a Notice by mail or e-mail and would like to receive a paper copy of our proxy materials, free of charge, please follow the instructions included in the Notice.

The Notice of Internet Availability of Proxy Materials is being mailed to our stockholders on or about April 17, 2013 and sent by e-mail to our stockholders who have opted for such means of delivery on or about April 17, 2013.

Please promptly submit your proxy over the Internet, by phone or by mail. You may revoke your proxy at any time before the 2013 Annual Meeting by following the procedures described in the proxy statement.

All stockholders are cordially invited to attend the meeting.

By Order of the Board of Directors,

/s/ Michael P. Gray

Michael P. Gray Chief Financial Officer, Secretary

Lexington, Massachusetts April 17, 2013

WHETHER OR NOT YOU PLAN TO ATTEND THE MEETING, WE URGE YOU TO VOTE YOUR SHARES OVER THE INTERNET OR BY TELEPHONE, OR TO COMPLETE, DATE, SIGN AND RETURN THE ENCLOSED PROXY CARD IN THE ACCOMPANYING ENVELOPE. NO POSTAGE NEED BE AFFIXED IF THE PROXY CARD IS MAILED IN THE UNITED STATES.

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#### CURIS, INC.

#### 4 Maguire Road Lexington, Massachusetts 02421

#### PROXY STATEMENT FOR ANNUAL MEETING OF STOCKHOLDERS

To Be Held on May 30, 2013

This proxy statement is furnished in connection with the solicitation by the board of directors of Curis, Inc. of proxies for use at the annual meeting of stockholders to be held on May 30, 2013 at 10:00 a.m., local time, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109 and at any adjournments thereof. Except where the context otherwise requires, references to "Curis," "we," "us," "our," and similar terms refer to Curis, Inc. and any of its subsidiaries.

Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting of Stockholders to be Held on May 30, 2013:

The proxy statement is available at www.proxyvote.com.

We will, upon written or oral request of any stockholder, furnish copies of our 2012 annual report to stockholders, except for exhibits, without charge. Please address all such requests to us at 4 Maguire Road, Lexington, Massachusetts 02421, Attention: Secretary or telephone: (617) 503-6500.

In accordance with Securities and Exchange Commission, or SEC, rules, instead of mailing a printed copy of our proxy materials to each stockholder of record, we are furnishing the proxy materials, including this proxy statement, our 2012 annual report and the proxy card for the 2013 annual meeting, to many of our stockholders of record as of the record date via the Internet. We will send the Notice of Internet Availability of Proxy Materials to these stockholders on or about April 17, 2013. The Notice of Internet Availability of Proxy Materials contains instructions for accessing and reviewing our proxy materials as well as instructions for voting your proxy via the Internet. If you prefer to receive printed copies of the proxy materials, you can request printed copies of the proxy materials by Internet, telephone or e-mail. If you choose to receive the print materials by mail, you can either (i) complete, date, sign and return the proxy card, (ii) vote via the Internet in accordance with the instructions on the proxy card or (iii) vote via telephone (toll free) in the United States or Canada in accordance with the instructions on the proxy card. Voting by Internet or telephone must be completed by 11:59 P.M.
Eastern Time on May 29, 2013. If you choose not to receive printed copies of the proxy materials, you can vote via the Internet in accordance with the instructions contained in the Notice of Internet Availability of Proxy Materials.

If you received a paper copy of these proxy materials, included with such copy is a proxy card or a voter instruction card for the annual meeting.

INFORMATION ABOUT THE ANNUAL MEETING AND VOTING

What is the purpose of the annual meeting?

At the annual meeting, stockholders will consider and vote on the following matters:

- 1. The election of three Class II directors for a term of three years expiring at the 2016 annual meeting of stockholders;
- 2. The approval of our amended and restated 2010 stock incentive plan;
- 3. The approval of an amendment to our restated certificate of incorporation;
- 4. The ratification of the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2013; and
- 5. The transaction of other business, if any, that may properly come before the annual meeting or any adjournment of the meeting.

#### Who can vote?

To be able to vote on the above matters, you must have been a stockholder of record at the close of business on April 1, 2013, the record date for the annual meeting. The number of shares entitled to vote at the meeting is 80,154,098 shares of our common stock, which is the number of shares that were issued and outstanding on the record date.

#### How many votes do I have?

Each share of our common stock that you owned on the record date entitles you to one vote on each matter that is voted on.

#### Is my vote important?

Your vote is important regardless of how many shares you own. Please take the time to read the instructions below and vote. Choose the method of voting that is easiest and most convenient for you and please cast your vote as soon as possible.

#### How can I vote?

Stockholder of record: Shares registered in your name. If you are a stockholder of record, that is, your shares are registered in your own name, not in "street name" by a bank or brokerage firm, then you can vote in any one of the following ways:

- 1. You may vote over the Internet. If you have Internet access, you may vote your shares from any location in the world at www.proxyvote.com, by following the instructions on that site or on the "Vote by Internet" instructions on the enclosed proxy card.
- 2. You may vote by telephone. You may vote your shares by calling 1-800-690-6903 and following the instructions provided, or by following the "Vote by Phone" instructions on the enclosed proxy card.
- 3. You may vote by mail. To vote by mail, you need to complete, date and sign the proxy card that accompanies this proxy statement and promptly mail it in the enclosed postage-prepaid envelope. You do not need to put a stamp on the enclosed envelope if you mail it in the United States. The persons named in the proxy card will vote the shares you own in accordance with your instructions on the proxy card you mail. If you return the proxy card, but do not give any instructions on a particular matter described in this proxy statement, the persons named in the proxy card will vote the shares you

- own in accordance with the recommendations of our board of directors. Our board of directors recommends that you vote FOR each of the four proposals.
- 4. You may vote in person. If you attend the annual meeting, you may vote by delivering your completed proxy card in person or you may vote by completing a ballot at the meeting. Ballots will be available at the meeting.

Beneficial owner: Shares held in "street name." If the shares you own are held in "street name" by a bank or brokerage firm, then your bank or brokerage firm, as the record holder of your shares, is required to vote your shares according to your instructions. In order to vote your shares, you will need to follow the directions your bank or brokerage firm provides you. Many banks and brokerage firms also offer the option of voting over the Internet or by telephone, instructions for which would be provided by your bank or brokerage firm on your vote instruction form. If you do not give instructions to your bank or brokerage firm, it will still be able to vote your shares with respect to certain "discretionary" items, but will not be allowed to vote your shares with respect to certain "non-discretionary" items. The ratification of the appointment of our independent registered public accounting firm (Proposal 4) is considered to be a discretionary item on which banks and brokerage firms may vote. The election of directors (Proposal 1), the amended and restated 2010 stock incentive plan (Proposal 2) and the amendment to our restated certificate of incorporation (Proposal 3) are considered to be non-discretionary items on which banks and brokerage firms may not vote, and therefore if you do not instruct your broker or representative regarding how you would like your shares to be voted, your bank or brokerage firm will not be able to vote on your behalf with respect to Proposals 1, 2 and 3. These shares will be treated as "broker non-votes." "Broker non-votes" are shares that are held in "street name" by a bank or brokerage firm that indicates on its proxy that it does not have discretionary authority to vote on a particular matter.

If you wish to come to the meeting to personally vote your shares held in "street name," you will need to obtain a proxy card from the holder of record (i.e., your brokerage firm or bank).

#### Can I change my vote after I have mailed my proxy card?

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Yes. If you are a stockholder of record, you can change your vote and revoke your proxy at any time before the polls close at the annual meeting by doing any one of the following things:

- signing and returning another proxy card with a later date;
- giving our corporate secretary a written notice before or at the meeting that you want to revoke your proxy; or
- · voting in person at the meeting.

Your attendance at the meeting alone will not revoke your proxy.

If you own shares in "street name," your bank or brokerage firm should provide you with appropriate instructions for changing your vote.

#### What constitutes a quorum?

In order for business to be conducted at the meeting, a quorum must be present. A quorum consists of the holders of a majority of the shares of common stock issued, outstanding and entitled to vote at the meeting, that is, at least 40,077,050 shares.

Shares of our common stock represented in person or by proxy (including broker non-votes and shares that abstain or do not vote with respect to one or more of the matters to be voted upon) will be counted for the purpose of determining whether a quorum exists.

If a quorum is not present, the meeting will be adjourned until a quorum is obtained.

#### What vote is required for each item?

**Proposal 1 – Election of Directors.** The affirmative vote of the holders of a plurality of the votes cast by the stockholders entitled to vote at the meeting is required for the election of directors.

**Proposal 2 – Approval of Amended and Restated 2010 Stock Incentive Plan.** The affirmative vote of the holders of a majority of the votes cast by the stockholders entitled to vote at the meeting is required to amend and restate our 2010 stock incentive plan.

**Proposal 3 – Approval of Amendment to Restated Certificate of Incorporation**. The affirmative vote of the holders of a majority of the votes cast by the stockholders entitled to vote at the meeting is required for the approval of the amendment to our restated certificate of incorporation.

**Proposal 4 – Ratification of Auditors**. The affirmative vote of the holders of a majority of the votes cast will be required for the approval of the ratification of the selection of the independent registered public accounting firm for the fiscal year ending December 31, 2013.

#### How will votes be counted?

Each share of common stock will be counted as one vote, whether executed by you directly or on a ballot voted in person at the meeting.

Shares that abstain from voting and broker non-votes will not be counted as votes in favor of, or with respect to, any of the proposals and will also not be counted as votes cast. Accordingly, abstentions and broker non-votes will have no effect on the outcome of any of the proposals.

#### Who will count the votes?

Broadridge Financial Solutions, Inc. will count, tabulate and certify the votes.

# How does the board of directors recommend that I vote on the proposals?

Our board of directors recommends that you vote:

**FOR** the election of three Class II directors for a term of three years expiring at the 2016 annual meeting of stockholders;

FOR the approval of our amended and restated 2010 stock incentive plan;

FOR the approval of the amendment to our restated certificate of incorporation; and

**FOR** the ratification of the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2013.

#### Will any other business be conducted at the annual meeting or will other matters be voted on?

We are not aware of any other business to be conducted or matters to be voted upon at the meeting. If any other matter properly comes before the meeting, the persons named in the proxy card that accompanies this proxy statement will exercise their judgment in deciding how to vote, or otherwise act, at the meeting with respect to that matter or proposal. Our bylaws establish the process for a stockholder to bring a matter before a meeting. See "Stockholder Proposals for 2014 Annual Meeting" on page 59 of this proxy statement.

#### Where can I find the voting results?

We will report the voting results from the annual meeting in a Form 8-K filed with the SEC within four business days following the annual meeting.

#### Who bears the costs of soliciting proxies?

We will bear the costs of soliciting proxies. In addition to solicitations by mail, our directors, officers and regular employees may, without additional remuneration, solicit proxies by telephone, facsimile and personal interviews. We will also request brokerage houses, custodians, nominees and fiduciaries to forward copies of the proxy material to those persons for whom they hold shares and request instructions for voting the proxies. We will reimburse such brokerage houses and other persons for their reasonable expenses in connection with this distribution.

#### How can I obtain a copy of Curis' Annual Report on Form 10-K?

Our Annual Report on Form 10-K is available in the "Investors" section of our website at www.curis.com. Alternatively, if you would like us to send you a copy, without charge, please contact:

Curis, Inc. 4 Maguire Road Lexington, MA 02421 Attention: Secretary (617) 503-6500

If you would like us to send you a copy of the exhibits listed on the exhibit index of the Annual Report on Form 10-K, we will do so upon your payment of our reasonable expenses in furnishing a requested exhibit.

#### Whom should I contact if I have any questions?

If you have any questions about the annual meeting or your ownership of our common stock, please contact our secretary at the address or telephone number listed above.

#### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information, as of January 31, 2013, with respect to the beneficial ownership of shares of our common stock by:

• each person known to us to beneficially own more than 5% of the outstanding shares of common stock,

- each director named in this proxy statement,
- each of our principal executive officer, our principal financial officer, and the two other most highly
  compensated executive officers who were serving as executive officers on December 31, 2012, whom
  we refer to collectively as our "named executive officers," and
- all directors and executive officers as a group.

The number of shares of common stock beneficially owned by each person is determined under rules promulgated by the SEC and includes shares over which the indicated beneficial owner exercises voting and/or investment power. For each person named in the table, the number in the "Shares Acquirable Within 60 Days" column consists of shares underlying stock options or warrants that may be exercised within 60 days after January 31, 2013. Such options and warrants are deemed outstanding for computing the percentage ownership of the person holding the options but are not deemed outstanding for computing the percentage ownership of any other person. Unless otherwise indicated, we believe that each stockholder in the table has sole voting and investment power over the shares listed. The inclusion in the table of any shares does not constitute an admission of beneficial ownership of those shares by the named stockholder. For each person, the "Number of Shares Beneficially Owned" column may include shares of common stock attributable to the person due to that person's voting or investment power or other relationship.

Unless otherwise indicated, the address for each of the stockholders in the table below is c/o Curis, Inc., 4 Maguire Road, Lexington, Massachusetts 02421.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned (1)	Shares Acquirable + Within 60 Days	Total Number of Shares Beneficially Owned	Percent of Shares Beneficially Owned (2)
5% Stockholders:				
First Eagle Investment Management,				
LLC (3)	16,676,456	245,073	16,921,529	21.1%
BlackRock, Inc. (4)	5,327,891		5,327,891	6.7%
The Vanguard Group, Inc. (5)	4,604,229		4,604,229	5.8%
Directors and Named Executive Officers:				
James R. McNab, Jr. (6)	1,379,688	224,166	1,603,854	2.0%
Susan B. Bayh	20,000	313,211	333,211	*
Martyn D. Greenacre	35,138	324,166	359,304	*
Kenneth I. Kaitin, Ph.D	26,800	219,166	245,966	*
Robert E. Martell, M.D., Ph.D.	_	63,541	63,541	*
Kenneth J. Pienta, M.D. (7)		42,188	42,188	*
Marc Rubin, M.D.	26,596	96,353	122,949	*
James R. Tobin	124,251	201,666	325,917	*
Daniel R. Passeri	150,750	2,841,999	2,992,749	3.6%
Michael P. Gray	86,613	1,438,745	1,525,358	1.9%
Maurizio Voi, M.D	_	134,374	134,374	*
Mark W. Noel		682,999	710,539	*
All current directors and executive				
officers as a group (12 persons)	1,877,376	6,582,574	8,459,950	9.8%

<sup>\*</sup> Less than 1% of the outstanding common stock.

- (1) None of our directors or named executive officers has pledged any of their shares as security.
- (2) The percent of ownership for each stockholder on January 31, 2013 is calculated by dividing (1) the stockholder's Total Beneficial Ownership (i.e., the total number of shares beneficially owned plus the shares acquirable within 60 days) by (2) the sum of 80,080,281 shares of our common stock that were outstanding on January 31, 2013 plus shares of common stock subject to options, or warrants held by such person that will be exercisable within 60 days of January 31, 2013.
- (3) First Eagle Investment Management, LLC ("FEIM") (formerly known as Arnhold and S. Bleichroeder Advisers, LLC), may be deemed to be the beneficial owner of all such shares (assuming exercise of warrants to acquire 245,073 shares), as a result of acting as investment adviser to various clients. 21 April Fund, Ltd., a Cayman Islands company for which FEIM acts as investment adviser, may be deemed to beneficially own 7,445,991 of the 16,921,529 shares (assuming exercise of warrants to acquire 68,250 shares). This information is based on a Schedule 13G/A filed on February 11, 2013 by FEIM. The principal business address of FEIM is 1345 Avenue of the Americas, New York, New York 10105.
- (4) This information is based on a Schedule 13G/A filed on February 6, 2013 by BlackRock, Inc., the parent holding company of BlackRock Institutional Trust Company, N.A., BlackRock Fund Advisors, BlackRock Advisors LLC, BlackRock Investment Management LLC, BlackRock Asset Management Canada Limited, and BlackRock Japan Co. Ltd. The principal business address of BlackRock, Inc. is 40 East 52nd Street, New York, New York 10022.
- (5) The Vanguard Group, Inc. may be deemed to be the beneficial owner of all such shares as a result of acting as investment adviser to Vanguard Fiduciary Trust Company and Vanguard Investments Australia, Ltd. Vanguard Fiduciary Trust Company, a wholly-owned subsidiary of The Vanguard Group, Inc., may be deemed to beneficially own 127,972 of the 4,604,229 shares. Vanguard Investments Australia, Ltd., a wholly-owned subsidiary of the Vanguard Group, Inc., may be deemed to beneficially own 1,500 of the 4,604,229 shares. This information is based on a Schedule 13G filed on February 12, 2013 by The Vanguard Group, Inc. The principal business address of The Vanguard Group, Inc. is 100 Vanguard Boulevard, Malvern, Pennsylvania 19355.
- (6) Includes 1,079,688 shares held directly by Mr. McNab, 100,000 shares held by the McNab Family LLC, and 200,000 shares held by the JR & MW McNab Operating LP.
- (7) Dr. Pienta was elected to our board of directors on March 7, 2013.

#### PROPOSAL 1—ELECTION OF DIRECTORS

#### **Directors and Nominees for Directors**

Our board of directors is divided into three classes, with one class being elected each year and members of each class holding office for a three-year term. Our board of directors currently consists of three Class I directors, James R. McNab, Jr., Kenneth J. Pienta and James R. Tobin, three Class II directors, Robert E. Martell, Daniel R. Passeri and Marc Rubin, and three Class III directors, Susan B. Bayh, Martyn D. Greenacre and Kenneth I. Kaitin. The Class I, Class II, and Class III directors will serve until the annual meetings of stockholders to be held in 2015, 2013 and 2014 respectively, and until their respective successors are elected and qualified. At the annual meeting, Class II directors will stand for reelection.

Our board of directors has nominated Dr. Robert E. Martell, Mr. Daniel R. Passeri and Dr. Marc Rubin as nominees for reelection as Class II directors, each to serve for three-year terms, until the 2016 annual meeting of stockholders or until their respective successors are elected and qualified. Each of the nominees is currently a director, although Drs. Martel and Rubin are being nominated as directors for the first time. In September 2011, our board appointed Dr. Martel as a new director to fill a vacancy. Dr. Martel was originally proposed to the nominating and governance committee by Dr. Kaitin. In June 2010, our board appointed Dr. Rubin as a new director to fill a vacancy. Dr. Rubin was originally proposed to the nominating and governance committee by Dr. Kaitin. All of the nominees have indicated their willingness to serve, if elected; however, if any nominee should be unable to serve, the shares of common stock represented by proxies will be voted for a substitute nominee designated by the board of directors.

Below are the names, ages and certain other information for each member of the board, including the nominees for election as Class II directors. There are no familial relationships among any of our directors, nominees for director and executive officers. In addition to the detailed information presented below for each of our directors, we also believe that each of our directors is qualified to serve on our board and has the integrity, business acumen, knowledge and industry experience, diligence, freedom from conflicts of interest and the ability to act in the interests of our stockholders.

The following table sets forth our directors and their respective ages and positions:

Name	Age	Position
Susan B. Bayh	53	Director
Martyn D. Greenacre (2)(3)	71	Director
Kenneth I. Kaitin, Ph.D. (1)(2)	60	Director
Robert E. Martell, M.D., Ph.D. (1)(4)	50	Director
James R. McNab, Jr. (3)	69	Chairman of the Board
Daniel R. Passeri	52	Chief Executive Officer, Director
Kenneth J. Pienta, M.D. (5)	53	Director
Marc Rubin, M.D. (2)(3)(4)	58	Director
James R. Tobin (1)	68	Director

- (1) Member of the compensation committee.
- (2) Member of the nominating and corporate governance committee.
- (3) Member of the audit committee.
- (4) Member of the science and technology committee.
- (5) Dr. Pienta was elected to our board of directors on March 7, 2013.

Susan B. Bayh has served on our board since October 2000. From 1994 to 2001, Ms. Bayh served as the Commissioner of the International Commission between the United States and Canada, overseeing compliance with environmental and water level treaties for the United States-Canadian border. From 1994 to 2004, Ms. Bayh also served as Distinguished Visiting Professor at the College of Business Administration at Butler University. From 1989 to 1994, Ms. Bayh served as an attorney in the Pharmaceutical Division of Eli Lilly and Company, a pharmaceutical company. Ms. Bayh serves as a director of Dendreon Corporation, Wellpoint, Inc. and Emmis Communications Corporation. Previously, Ms. Bayh served as a director of Nastech Pharmaceutical Company Inc. and MDRNA, Inc. Ms. Bayh received a J.D. from the University of Southern California Law Center and a B.A. from the University of California at Berkeley. We believe that Ms. Bayh's qualifications to serve on our board include her experience in regulatory and compliance matters as well as her considerable experience as a director of other public companies, including companies that are focused on the research and development of cancer therapies

Martyn D. Greenacre has served on our board since February 2000 and was a director of Creative BioMolecules, Inc., a predecessor life science company, from June 1993 to July 2000. Mr. Greenacre has served as Chairman of Life Mist L.L.C., a privately-held company in the field of fire suppression, since September 2001. From June 1997 to June 2001, Mr. Greenacre was Chief Executive Officer of Delsys Pharmaceutical Corporation, a drug formulation company. From 1993 to 1997, Mr. Greenacre was President and Chief Executive Officer of Zynaxis, Inc., a biopharmaceutical company. Mr. Greenacre also serves as a director of Neostem, Inc., Acusphere, Inc., and Formula Pharmaceuticals. Previously, Mr. Greenacre served as a director of Cephalon, Inc. and Orchestra Therapeutics, Inc., and as a director and Chairman of BMP Sunstone Corporation. Mr. Greenacre received an M.B.A. from Harvard Business School and a B.A. from Harvard College. We believe that Mr. Greenacre's qualifications to serve on our board include his years of experience as President and Chief Executive Officer of various biotech and pharmaceutical companies as well as his experience as a director of other public companies.

Kenneth I. Kaitin, Ph.D. has served on our board since November 2003. Since 1998, Dr. Kaitin has been the Director of the Tufts Center for the Study of Drug Development, an academic drug policy research group providing strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of the drug development process. Since 2010, Dr. Kaitin has held a primary appointment as Research Professor at the Tufts University School of Medicine, as well as secondary appointments as Professor of Medicine and Professor of Pharmacology and Experimental Therapeutics at Tufts University School of Medicine. Since 1999, he has served on the faculty of the European Center for Pharmaceutical Medicine at the University of Basel, and since 2006 he has been a visiting lecturer at the Tuck School of Business at Dartmouth College. From 2003 to 2009, Dr. Kaitin was an Associate Professor of Medicine at the Tufts University School of Medicine. Dr. Kaitin has written extensively on a broad range of drug development issues and has provided public testimony before the U.S. Congress in hearings on pharmaceutical innovation and FDA reform. An internationally recognized expert on the science of drug development, Dr. Kaitin is regularly quoted in the business and trade press on R&D trends in the research-based drug industry and new models of innovation. He is a former Editor-in-Chief of the Drug Information Journal and from 1997 to 1998 he was President of the Drug Information Association. He is currently Editor-in-Chief of Expert Review of Clinical Pharmacology, and he serves on the editorial boards of a number of peer-review journals. Dr. Kaitin serves as an expert consultant to the U.S. Department of Defense on Bioterror Countermeasure issues. Dr. Kaitin also serves as a director of Bio-Tree Systems, Inc., a privately-held informatics company, Centerphase Solutions, Inc., a privately-held information technology company, and New England Healthcare Institute, a non-profit organization. Previously, Dr. Kaitin served as a director of Phase Forward Inc. and Erevnos Corporation. Dr. Kaitin received an M.S. and

Ph.D. in pharmacology from the University of Rochester and a B.S. from Cornell University. We believe that Dr. Kaitin's qualifications to serve on our board include his expertise in the economics of drug development and biopharmaceutical innovation and his extensive knowledge on a broad range of drug development and lifesciences industry issues.

Robert E. Martell, M.D., Ph.D. has served on our board since September 2011. Dr. Martell is a practicing medical oncologist at Tufts Medical Center and has served as Chief Medical Officer at Tesaro, Inc. since September 2012. Dr. Martell is also an Adjunct Associate Professor of Medicine at the Tufts University School of Medicine, a position he has held since September 2012. From September 2009 to September 2012, Dr. Martell was employed at Tufts Medical Center, serving as both the Director of the Neely Center for Clinical Cancer Research, overseeing oncology clinical research, and the Leader of the Cancer Center's Program in Experimental Therapeutics, where he was responsible for developing the center's phase I oncology clinical development program. From September 2009 to September of 2012, Dr. Martell was also an Adjunct Associate Professor of Medicine at the Tufts University School of Medicine. From 2005 to 2009, Dr. Martell served as Vice President and Chief Medical Officer of MethylGene, a publicly-traded biotechnology company focused on the development of cancer therapeutics. From 2002 to May 2005, Dr. Martell also served as Director of Oncology Global Clinical Research at Bristol-Myers Squibb Company. From 2001 to 2005, Dr. Martell served concurrently as Assistant Clinical Professor of Oncology at Yale University School of Medicine and Staff Physician at the Veterans Affairs hospital. From 2000 to 2002, Dr. Martell worked at Bayer Pharmaceutical Division, where he oversaw phase I and phase II clinical studies. Dr. Martell received a B.A. in chemistry from Kalamazoo College, a Ph.D. in pharmacology from the University of Michigan, and an M.D. from Wayne State University. He completed his internal medicine internship and residency and medical oncology fellowship at Duke University Medical Center. We believe that Dr. Martell's qualifications to serve on our board include his expertise in oncology patient care as well as his industry experience in large pharmaceutical and smaller biotechnology companies and that his insights and perspectives are valuable to a small biotechnology company such as Curis.

James R. McNab, Jr. has served on our board since February 2000 and has served as Chairman of our board since May 2002. Mr. McNab is a co-founder and served as the chairman of the board of directors of Reprogenesis, Inc., a predecessor life science company, from July 1996 to July 2000. Since 1998, Mr. McNab has served as Chief Executive Officer and Chairman of Palmetto Pharmaceuticals, Inc., formerly eNOS Pharmaceuticals, Inc., a privately-held drug discovery company of which he is a co-founder. Since January 2009, Mr. McNab has served as executive chairman of FirstString Research, Inc., a privately-held biopharmaceutical company. In addition, Mr. McNab is a co-founder of other privately-held companies, including Sontra Medical Corporation, a drug delivery company, and Parker Medical Associates, a manufacturer and worldwide supplier of orthopedic and sports-related products. Mr. McNab received a B.A. in economics from Davidson College and an M.B.A. from the University of North Carolina at Chapel Hill. We believe that Mr. McNab's qualifications to serve on our board include his decades of experience as chairman, founder and/or Chief Executive Officer of various pharmaceutical, medical device and biotechnology companies, including his experience as co-founder of one of our predecessor companies. Mr. McNab has also founded and managed companies in other industries and we believe that his broad range of entrepreneurial creation and oversight is valuable to a small biotechnology company such as Curis.

Daniel R. Passeri has served as our Chief Executive Officer since September 2001, served as our President from September 2001 to February 2013, and served as a director since September 2001. 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 received a J.D. from the National Law Center at George Washington University, an M.Sc. in biotechnology from the Imperial College of Science, Technology and Medicine at the University of London and a B.S. in biology from Northeastern University. We believe that Mr. Passeri's qualifications to serve on our board include his deep knowledge of the company, having served in a variety of management positions since 2000 and as a member of our board since 2001, as well as his extensive experience in corporate strategy and development, intellectual property strategy and oversight, and technology licensing, as each of these elements are critical to our overall business strategy.

Kenneth J. Pienta, M.D. has served on our board since March 2013. Dr. Pienta has served as the Donald S. Coffey Professor of Urology, Professor of Oncology, Pharmacology and Molecular Sciences and as the Director of Research for the Brady Urological Institute at the Johns Hopkins University School of Medicine since March 2013. Prior to his appointment at the Johns Hopkins University School of Medicine, Dr. Pienta served as the Associate Vice President for Research, Health Sciences for the University of Michigan from January 2012 to February 2013, and as the Director of Precision Medicine for the Michigan Center for Translational Pathology from July 2008 to February 2013. From July 1995 to February 2013, Dr. Pienta served as the Director of the Prostate Specialized Program of Research Excellence (SPORE) at The University of Michigan. Dr. Pienta is involved in research to define the tumor microenvironment of cancer metastases, as well as developing new therapies for cancer. Dr. Pienta is a two-time American Cancer Society Clinical Research Professor Award recipient, is the author of more than 350 peer-reviewed articles and has been the principal investigator on numerous local and national clinical trials. Dr. Pienta received a B.A. in human biology from Johns Hopkins University and an M.D. from the Johns Hopkins University School of Medicine. We believe that Dr. Pienta's qualifications to serve on our board include his expertise in oncology patient care as well as his unique understanding of precision therapeutic approaches to cancer treatment and that his insights and perspectives are valuable to a small biotechnology company such as Curis.

Marc Rubin, M.D. has served on our board since June 2010. Since March 2009, Dr. Rubin has served as Executive Chairman of Titan Pharmaceuticals, Inc., a biopharmaceutical company, and he served as its President and Chief Executive Officer from October 2007 to January 2009. From June 2006 to February 2007, Dr. Rubin served as Head of Global Research and Development for Bayer Schering Pharma AG, a pharmaceutical company, as well as a member of the Executive Committee of Bayer Healthcare, a pharmaceutical and medical products company and subsidiary of Bayer AG, and the Board of Management of Bayer Schering Pharma AG. From October 2003 until the merger of Bayer AG and Schering AG in June 2006, Dr. Rubin was a member of the Executive Board of Schering AG, as well as Chairman of Schering Berlin Inc. and President of Berlex Pharmaceuticals, a division of Schering AG. From 1990 to August 2003, Dr. Rubin held various positions in global clinical and commercial development at GlaxoSmithKline plc, as well as the position of Senior Vice President of Global Clinical Pharmacology & Discovery Medicine from 2001 to 2003. Prior to his pharmaceutical industry career, Dr. Rubin completed subspecialty training and board certification in both medical oncology and infectious diseases at the National Cancer Institute within the National Institutes of Health from 1983 to 1986. From 1986 to 1989, Dr. Rubin also served as an Investigator and on the Senior Staff of the infectious diseases section at the National Cancer Institute. Dr. Rubin also serves as a director of FirstString Research, Inc., Galectin Therapeutics, Gemmus Pharma and the Rogosin Institute. Previously, Dr. Rubin served as a director of Medarex, Inc. and Surface Logix, Inc. Dr. Rubin holds an M.D. from Cornell University Medical College. We believe that Dr. Rubin's qualifications to serve on our board include his extensive experience in

clinical development as well as his medical, commercial and scientific expertise having held executive-level clinical development positions with Bayer Schering Pharma AG, Schering AG and GlaxoSmithKline plc.

James R. Tobin has served on our board since February 2000. From 1995 to July 2000, Mr. Tobin was a member of the board of directors of Creative BioMolecules, Inc., a predecessor life science company, Mr. Tobin is currently retired. From March 1999 to July 2009, Mr. Tobin served as Chief Executive Officer and President of Boston Scientific Corporation, a medical device company. Mr. Tobin was employed by Biogen, Inc. (now Biogen Idec), as President and Chief Executive Officer from February 1997 to December 1998 and President and Chief Operating Officer from February 1994 to February 1997. Prior to joining Biogen, Mr. Tobin was employed by Baxter International Inc., a health care products company, where he served as President and Chief Operating Officer from 1992 to 1994, as Executive Vice President from 1988 to 1992 and in various management positions prior to 1988. Mr. Tobin also serves as a director of Aptus Endosystems, Medical Simulations, Inc. and TransMedics. During the past five years, Mr. Tobin served as a director of Boston Scientific Corporation and Applera Corporation. Mr. Tobin received an M.B.A. from Harvard Business School and a B.A. from Harvard College. We believe that Mr. Tobin's qualifications to serve on our board include his decades of experience as President and Chief Executive Officer or Chief Operating Officer of three large biotechnology and medical device companies. In addition, his qualifications include his past experience as a director of Boston Scientific Corporation and one of our predecessor companies, as well as his experience in corporate strategy and organizational expertise.

#### **Board Recommendation**

OUR BOARD OF DIRECTORS BELIEVES THAT THE ELECTION OF ROBERT E. MARTELL, DANIEL R. PASSERI AND MARC RUBIN TO SERVE AS CLASS II DIRECTORS IS IN THE BEST INTERESTS OF CURIS AND OUR STOCKHOLDERS AND, THEREFORE, THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT THE STOCKHOLDERS VOTE "FOR" THE NOMINEES.

#### **CORPORATE GOVERNANCE**

Our board of directors believes that good corporate governance is important to ensure that Curis is managed for the long-term benefit of stockholders. This section describes key corporate governance guidelines and practices that our board of directors has adopted. Complete copies of our corporate governance guidelines, committee charters and code of conduct are available on the Investors – Governance section of our website, <a href="https://www.curis.com">www.curis.com</a>. Alternatively, you can request a copy of any of these documents by writing to our secretary at the following address: Curis, Inc., 4 Maguire Road, Lexington, MA 02421.

#### **Corporate Governance Guidelines**

Our board of directors has adopted corporate governance guidelines to assist in the exercise of its duties and responsibilities and to serve the best interests of Curis and our stockholders. These guidelines, which provide a framework for the conduct of the board of directors' business, provide that:

- the board of directors' principal responsibility is to oversee the management of Curis;
- a majority of the members of the board of directors shall be independent directors;
- the independent directors shall meet regularly in executive session;

- directors have full and free access to management and, as necessary and appropriate, independent advisors;
- all directors are encouraged to participate in continuing director education on an ongoing basis; and
- periodically, the board of directors and its committees will conduct a self-evaluation to determine
  whether they are functioning effectively.

#### **Determination of Independence**

Under applicable Nasdaq Stock Market rules, a director will only qualify as an "independent director" if, in the opinion of our board, that person does not have a relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities as a director.

Our board has determined that none of Ms. Bayh, Mr. Greenacre, Dr. Kaitin, Dr. Martell, Mr. McNab, Dr. Rubin or Mr. Tobin has a relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Stock Market Rules.

#### **Board Meetings and Attendance**

Our corporate governance guidelines provide that directors are expected to attend the annual meeting of stockholders. All directors attended the 2012 annual meeting of stockholders, except for Dr. Pienta who was elected after the 2012 annual meeting. The board met thirteen times during the fiscal year ended December 31, 2012, either in person or by teleconference. During the fiscal year ended December 31, 2012, all of our directors attended at least 75% of our board meetings and meetings of the committees on which he or she then served.

#### **Board Leadership Structure**

Our board has chosen to separate the role of our chief executive officer and the role of chairman of our board. We believe that this separation is appropriate since our chief executive officer is responsible for the strategic direction of our company, while the chairman of our board is responsible for overseeing the function of the board and for providing guidance to our chief executive officer as needed.

#### Board's Role in Risk Oversight

Our board of directors oversees our risk management processes directly and through its committees. Our management is responsible for risk management on a day-to-day basis. Our board of directors and its committees oversee the risk management activities of management. They fulfill this duty by discussing with management the policies and practices utilized by management in assessing and managing risks and providing input on those policies and practices. In general, our (i) board of directors oversees risk management activities relating to business strategy, acquisitions, capital allocation, organizational structure and certain operational risks, (ii) audit committee oversees risk management activities related to financial controls, (iii) compensation committee oversees risk management activities relating to our compensation policies, programs and practices and management succession planning, and (iv) nominating and corporate governance committee oversees risk management activities relating to board of directors composition and corporate governance policies and procedures. Each committee reports to our full board of directors on a regular basis, including reports with respect to the committee's risk oversight activities as appropriate.

#### **Board Committees**

Our board has established three standing committees – audit, compensation, and nominating and corporate governance – each of which operates under a charter that has been approved by our board. Our board of directors has also established a science and technology committee. Current copies of each committee's charter are posted on the Investors – Governance section of our website, <u>www.curis.com</u>.

Our board has determined that all of the members of each of the board of directors' three standing committees are independent as defined under the rules of the Nasdaq Stock Market, including, in the case of all members of the audit committee, the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

#### Audit Committee

The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving all audit and non-audit services of our independent registered public accounting firm, except for de minimis non-audit services which are approved in accordance with applicable SEC rules, including meeting with our independent registered public accounting firm prior to the annual audit to discuss the planning and staffing of the audit;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of certain reports from such firm;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures, earnings releases and other publicly disseminated financial information;
- reviewing and discussing with our independent registered public accounting firm matters concerning
  the quality, not just the acceptability, of our accounting determinations, particularly with respect to
  judgmental areas;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- establishing policies regarding hiring employees from the independent auditor and procedures for the receipt and retention of accounting-related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management on a quarterly basis;
- reviewing and approving or ratifying any related person transactions;
- establishing, and periodically reviewing, complaint procedures for (i) the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters; and (ii) the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters; and

 preparing the audit committee report required by SEC rules, which is included on page 20 of this proxy statement.

The members of the audit committee during fiscal 2012 were Ms. Bayh, Mr. Greenacre (Chair) and Mr. McNab. The audit committee met eight times during the fiscal year ended December 31, 2012. The current members of the audit committee are Mr. Greenacre (Chair), Mr. McNab and Dr. Rubin. The board of directors has determined that Mr. Greenacre is an "audit committee financial expert" as defined by applicable SEC rules.

#### Compensation Committee

The compensation committee's responsibilities include:

- determining the chief executive officer's compensation;
- reviewing and approving the compensation of our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to the board with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis,"
   which is included beginning on page 23 of this proxy statement;
- preparing the compensation committee report required by SEC rules, which is included on page 45 of this proxy statement; and
- reviewing and making recommendations to the board with respect to management succession planning.

The processes and procedures followed by our compensation committee in considering and determining executive and director compensation are described below under the heading "Executive and Director Compensation Processes."

The members of the compensation committee during fiscal 2012 were Ms. Bayh, Dr. Kaitin and Mr. Tobin (Chair). The compensation committee met seven times during the fiscal year ended December 31, 2012. The current members of the compensation committee are Dr. Kaitin, Dr. Martell and Mr. Tobin (Chair).

## Nominating and Corporate Governance Committee

The nominating and corporate governance committee's responsibilities include:

- identifying individuals qualified to become board members;
- recommending to the board the persons to be nominated for election as directors and to each of the board's committees; and
- · overseeing an annual evaluation of the board.

The processes and procedures followed by the nominating and corporate governance committee in identifying and evaluating director candidates are described below under the heading "Director Nomination Process."

The members of the nominating and corporate governance committee are Dr. Kaitin (Chair), Mr. Greenacre and Dr. Rubin. The nominating and corporate governance committee met two times during the fiscal year ended December 31, 2012.

## Science and Technology Committee

The science and technology committee's responsibilities include:

- reviewing, evaluating, and advising the board and management regarding the long-term strategic goals
  and objectives and the quality and direction of the company's research and development programs;
- monitoring and evaluating trends in research and development, and recommending to the board and management emerging technologies for building the company's technological strength;
- recommending approaches to acquiring and maintaining technology positions;
- advising the board and management on the scientific aspects of business development;
- regularly reviewing the company's research and development pipeline;
- assisting the Board with its oversight responsibility for enterprise risk management in areas affecting the company's research and development; and
- reviewing such other topics as delegated to the committee from time to time.

The members of the science and technology committee are Dr. Rubin and Dr. Martell.

# **Executive and Director Compensation Processes**

The compensation committee oversees our compensation programs. In this capacity, the compensation committee determines and approves all compensation decisions related to our executive officers. In addition, the compensation committee periodically reviews and makes recommendations to the board with respect to director compensation. With respect to the grant of equity compensation awards and the grant of cash awards, if any, structured under our stock incentive plan as performance-based compensation that is exempt from Section 162(m) of the Internal Revenue Code of 1986, as amended, the compensation committee may form, and delegate authority to, one or more subcommittees as it deems appropriate from time to time under the circumstances (including (a) a subcommittee consisting of a single member and (b) a subcommittee consisting of at least two members, each of whom qualifies as a "non-employee director," as such term is defined from time in Rule 16b-3 promulgated under the Exchange Act, and an "outside director," as such term is defined from time to time in Section 162(m) of the Internal Revenue Code of 1986, as amended). The compensation committee did not form or delegate authority to any subcommittees during the fiscal year ending December 31, 2012.

The compensation committee has the authority to retain and terminate any compensation consultant to be used to assist in the evaluation of executive officer compensation and has the sole authority to approve the consultant's fees and other retention terms. The compensation committee also has authority to commission compensation surveys or studies as the need arises. Periodically, the compensation committee retains an independent third party compensation consultant to review director and officer compensation. The compensation committee engaged Towers Watson, a compensation consultant, in September 2012 to review director and officer compensation and to evaluate director and officer stock ownership and review industry practice relating to stock ownership guidelines.

Compensation committee meetings typically have included, for all or a portion of each meeting, our chief financial officer and, for meetings in which executive officer compensation decisions are made, the chairman of our board and our chief executive officer. The compensation committee typically seeks the chairman's input in compensation matters involving our chief executive officer. The chief executive officer provides input on all other executive officer compensation matters including the appropriate mix of compensation for such other officers. The chief executive officer and the chief financial officer do not attend the portion of any meeting during which any decisions regarding their respective compensation are made.

#### Risks Arising from Compensation Policies and Practices

Employee compensation generally consists of salary, stock option awards and, depending on overall company performance and the successful achievement of objectives set forth in an annual short-term incentive program, cash bonus payments. We have reviewed our compensation policies and practices for all employees and have concluded that any risks arising from our policies and programs are not reasonably likely to have a material adverse effect on our company.

#### **Director Nomination Process**

The process followed by the nominating and corporate governance committee to identify and evaluate director candidates includes requests to board members and others for recommendations, meetings from time to time to evaluate biographical information and background material relating to potential candidates, and interviews of selected candidates by members of the nominating and corporate governance committee and the board.

In considering whether to recommend any particular candidate for inclusion in the board's slate of recommended director nominees, the nominating and corporate governance committee will apply the criteria set forth in its charter. These criteria include the candidate's integrity, business acumen, knowledge of our business and industry, experience, diligence, freedom from conflicts of interest and the ability to act in the interests of all stockholders. Our nominating and corporate governance charter provides that the value of diversity on our board should be considered by the nominating and corporate governance committee. The committee does not assign specific weights to particular criteria and no particular criterion is a prerequisite for each prospective nominee. We believe that the backgrounds and qualifications of our directors, considered as a group, should provide a composite mix of experience, knowledge and abilities that will allow the board to fulfill its responsibilities. We do not discriminate against candidates based on their race, religion, national origin, sex, sexual orientation, disability or any other basis proscribed by law.

We have adopted a policy under which stockholders may recommend individuals to the nominating and corporate governance committee for consideration as potential director candidates by submitting candidate names, together with appropriate biographical information and background materials and a statement as to whether the stockholder or group of stockholders making the recommendation has beneficially owned more than 5% of our common stock for at least a year as of the date such recommendation is made, to the Nominating and Corporate Governance Committee, c/o Secretary, Curis, Inc., 4 Maguire Road, Lexington, MA 02421. Assuming that appropriate biographical and background material has been provided on a timely basis, the committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates submitted by others. If the board determines to nominate a stockholder-recommended candidate and recommends his or her election, then his or her name will be included in our proxy card for the next annual meeting.

Stockholders also have the right under our bylaws to directly nominate director candidates, without any action or recommendation on the part of the committee or the board of directors, by following the procedures set forth under "Stockholder Proposals for 2014 Annual Meeting."

#### **Communicating with the Independent Directors**

The board will give appropriate attention to written communications that are submitted by stockholders, and will respond if and as appropriate. The chairman of the board of directors is primarily responsible for monitoring communications from stockholders and for providing copies or summaries to the other directors as he or she considers appropriate.

Communications are forwarded to all directors if they relate to important substantive matters and include suggestions or comments that the chairman of the board considers to be important for the directors to know. In general, communications relating to corporate governance and corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which we receive repetitive or duplicative communications.

Stockholders who wish to send communications on any topic to the board should address such communications to the Chairman of the Board of Directors, c/o Secretary, Curis, Inc., 4 Maguire Road, Lexington, MA 02421.

#### **Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. We have posted a current copy of the code on our website, www.curis.com. In addition, we intend to post on our website all disclosures that are required by law or NASDAQ stock market listing standards concerning any amendments to, or waivers of, any provision of the code. We have not had any waivers of any provision of this code as of the date of this proxy statement.

#### **Policies and Procedures for Related Person Transactions**

Our board has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which Curis is a participant, the amount involved exceeds \$120,000, and one of our executive officers, directors, director nominees or 5% stockholders (or their immediate family members), each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our chief financial officer and/or general counsel. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by the board's audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the audit committee will review, and, in its discretion, may ratify the related person transaction at the next meeting of the committee. The policy also permits the chairman of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings,

subject to ratification by the audit committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually. The audit committee will review and consider such information regarding the related person transaction as it deems appropriate under the circumstances.

The audit committee may approve or ratify the transaction only if the committee determines that, under all of the circumstances, the transaction is not inconsistent with Curis' best interests. The audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, the board has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity (whether or not the person is also a director of such entity), that is a participant in the transaction, where (a) the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, and (b) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction; and
- a transaction that is specifically contemplated by provisions of our charter or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by the compensation committee in the manner specified in its charter.

#### **Related Person Transactions**

We are party to a Drug Development Partnership and License Agreement for CUDC-906 and CUDC-908 (the "License Agreement"), effective as of February 24, 2012, with Guangzhou BeBetter Medicine Technology Company Ltd., a company organized under the laws of the People's Republic of China ("GBMT"). Dr. Changgeng Qian, our former Senior Vice President, Discovery and Preclinical Development, is the founder, owner, and legal representative of GBMT. Under the terms of the License Agreement, we have 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 CUDC-906 or CUDC-908 in the GBMT Territory (China, Macau, Taiwan and Hong Kong). In addition, we have granted to GBMT a non-exclusive, royalty-free manufacturing license, with the right to grant sublicenses subject to certain conditions, to manufacture CUDC-906 or CUDC-908 or any product containing CUDC-906 or CUDC-908 outside of the GBMT Territory solely to import the compounds or products into the GBMT Territory. We have agreed to pay up to \$400,000 under the License Agreement for certain IND-enabling activities, of which \$133,000 has been paid to date.

We are also a party to a Drug Development Partnership and License Agreement for CU-201 (the "CU-201 License Agreement"), effective as of November 1, 2012, with GBMT. Under the terms of the CU-201 License Agreement, we have 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-201 in the GBMT Territory (China, Macau, Taiwan and Hong Kong). In addition, we have granted to GBMT a non-exclusive, royalty-free manufacturing license, with the right to grant sublicenses subject to certain conditions, to manufacture CU-201 or any product containing CU-201 outside of the GBMT Territory solely to import the compounds or products into the GBMT Territory.

On March 7, 2013, our 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. In addition to his services as a member of our board of directors, we and Dr. Pienta are parties to a scientific advisory board agreement effective September 13, 2006, as amended from time to time, under which Dr. Pienta has served as a member of our scientific advisory board since September 2006 and as its chairman since June 2007. Pursuant to the scientific advisory board 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, Dr. Pienta served as a consultant to the company in the areas of corporate strategy and business development under which we paid Dr. Pienta \$10,000 per month. We and Dr. Pienta terminated the consulting agreement in connection with his election as a member of the board of directors. Since January 1, 2012, Dr. Pienta has received aggregate payments from the company of \$142,258 related to these two agreements.

#### **Audit Committee Report**

The audit committee has reviewed our audited financial statements for the fiscal year ended December 31, 2012, and has discussed these financial statements with our management and our independent registered public accounting firm.

Our management is responsible for the preparation of our financial statements and for maintaining an adequate system of disclosure controls and procedures and internal control over financial reporting for that purpose. Our independent registered public accounting firm is responsible for conducting an independent audit of our annual financial statements in accordance with the standards of the Public Company Accounting Oversight Board and issuing a report on the results of their audit. The audit committee is responsible for providing independent, objective oversight of these processes.

The audit committee has also received from, and discussed with, our independent registered public accounting firm various communications that our independent registered public accounting firm is required to provide to the audit committee, including the matters required to be discussed by the Statement on Auditing Standards No. 61, as amended (AICPA, Professional Standards, Vol. 1, AU section 380), as adopted by the Public Company Accounting Oversight Board in Rule 3200T. SAS 61, as amended, requires our independent registered public accounting firm to discuss with the audit committee, among other things, the following:

- · methods to account for significant unusual transactions;
- the effect of significant accounting policies in controversial or emerging areas for which there is a lack
  of authoritative guidance or consensus;
- the process used by management in formulating particularly sensitive accounting estimates and the basis for the auditors' conclusions regarding the reasonableness of those estimates; and
- disagreements with management over the application of accounting principles, the basis for management's accounting estimates and the disclosures in the financial statements.

The audit committee has received the written disclosures and the letter from our independent registered public accounting firm required by applicable requirements of the Public Company Accounting Oversight Board regarding our independent registered public accounting firm's communications with the audit committee concerning independence, and has discussed with the independent registered public accounting firm their independence from Curis.

Based on the review and discussions referred to above, the audit committee recommended to our board of directors that the audited financial statements be included in our Annual Report on Form 10-K for the year ended December 31, 2012.

Submitted by the audit committee of our board of directors.

Martyn D. Greenacre (Chair) Marc Rubin James R. McNab, Jr.

#### Independent Registered Public Accounting Firm's Fees and Other Matters

Independent Registered Public Accounting Firm's Fees

The following table summarizes the fees of PricewaterhouseCoopers LLP, our independent registered public accounting firm, billed to us for each of the last two fiscal years:

Fee Category	2012	2011
Audit Fees (1)	\$393,000	\$315,000
Audit-related fees (2)		56,500
All Other Fees (3)		1,800
Total Fees	\$426,800	\$373,300

- (1) Audit fees consist of fees for the audit of our financial statements, the audit of our internal control over financial reporting, the review of the interim financial statements included in our quarterly reports on Form 10-Q, and other professional services provided in connection with statutory and regulatory filings or engagements. 100% of the audit fees for 2012 and 2011 were pre-approved by the audit committee. These amounts exclude reimbursement of out of pocket expenses of \$3,195 and \$3,250 for 2012 and 2011, respectively.
- (2) Audit-related fees for 2012 and 2011 consist of fees associated with comfort letters for our at-the-market sales agreement entered into in July 2011. 100% of the audit-related fees for 2012 and 2011 were preapproved by the audit committee.
- (3) Other fees consist of an annual license fee for use of Comperio, accounting research software. None of the other fees incurred during 2012 and 2011 were for services provided under the de minimis exception to the audit committee pre-approval requirements. 100% of these fees for 2012 and 2011 were pre-approved by the audit committee.

#### Pre-Approval Policy and Procedures

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy generally provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the audit committee specifically approves the service in advance or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next 12 months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

The audit committee has also delegated to the chairman of the audit committee the authority to approve any audit or non-audit services to be provided to us by our independent registered public accounting firm. Any approval of services by a member of the audit committee pursuant to this delegated authority is reported on at the next meeting of the audit committee.

# EXECUTIVE AND DIRECTOR COMPENSATION AND RELATED MATTERS

#### **Compensation Discussion and Analysis**

This Compensation Discussion and Analysis describes our compensation strategy, policies, programs and practices for our named executive officers identified in the "Summary Compensation Table." Our named executive officers consist of Daniel R. Passeri, our chief executive officer, Michael P. Gray, our chief financial officer, Mark W. Noel, our vice president, technology management and intellectual property, and Maurizio Voi, M.D., our executive vice president, chief medical and chief development officer, whom we refer to collectively in this Compensation Discussion and Analysis as our "executive officers."

In February 2013, Ali Fattaey, Ph.D. was named our president and chief operating officer. See "Other 2013 Compensation Awards" below for a description of awards to Dr. Fattaey in connection with his appointment.

Compensation decisions for our executive officers are made by the compensation committee of our board of directors.

At our June 2011 annual meeting, we held a "say-on-pay" advisory stockholder vote on the compensation of our named executive officers. Our proposal regarding the say-on-pay vote was supported by our stockholders at this meeting. For compensation decisions made by our compensation committee in fiscal years 2011 and 2012 and to date in 2013, no specific component of our executive compensation program was altered based on the results of the say-on-pay vote. At the June 2011 annual meeting, stockholders also voted to hold a "say-on-pay" advisory stockholder vote every three years, meaning the next such vote will occur at the 2014 annual meeting. Our compensation committee and our board of directors believe that our executive compensation has been appropriately tailored to our business strategies, aligns pay with performance, and reflects best practices regarding executive compensation. The committee will continue to consider stockholder sentiments about our core principles and objectives when determining executive compensation.

#### **Executive Summary**

The compensation paid to our named executive officers in 2012 reflected our primary compensation objectives of attracting and retaining key executive officers critical to our long-term success, recognizing and rewarding overall company performance and each executive officer's individual performance and level of responsibility, as well as continuing to align our executive officers' incentives with stockholders' interests.

#### 2012 Corporate Results

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We and our collaborators achieved a number of our key corporate goals and objectives in 2012 including the following:

• Our collaborator Genentech, a member of the Roche Group, received U.S. Food & Drug Administration, or FDA, approval of Erivedge® (vismodegib). Erivedge, a hedgehog pathway inhibitor, was approved for the treatment of adults with basal cell carcinoma 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 addition, Roche has filed regulatory submissions seeking the approval of Erivedge in several other territories, including Europe and Australia. In 2012, we received an aggregate of \$14 million in milestone payments and approximately \$1.5 million in royalty revenues from Genentech's 2012 net sales of Erivedge under this collaboration.

- We completed our preclinical testing of CUDC-907, our dual HDAC and PI3K inhibitor, and filed an
  investigational new drug, or IND, application with the FDA to begin phase I clinical testing. We treated
  the first patient in the phase I clinical study in January 2013. As a result of this progress, we earned
  \$1.1 million in milestone payments under our agreement with The Leukemia & Lymphoma Society, or
  LLS.
- We acquired from Genentech the exclusive, worldwide rights for the further development and commercialization of CUDC-427 (GDC-0917), a small molecule that is designed to promote cancer cell death by antagonizing inhibitor of apoptosis, or IAP, proteins. We view this asset as an important expansion of our pipeline of development candidates.
- We, through our subsidiary Curis Royalty, LLC, entered into a \$30 million debt transaction with BioPharma Secured Debt Fund II Sub, S.àr.l, or BioPharma-II, an investment fund managed by Pharmakon Advisors that is secured by certain future Erivedge royalty payments that we expect to receive under our collaboration agreement with Genentech.
- Our licensee Debiopharm initiated a phase Ib expansion study of Hsp90 inhibitor Debio 0932 as well as a phase I/II clinical study of Debio 0932 in patients with advanced non-small cell lung cancer.
- We continued enrollment in our ongoing phase I clinical study of intravenous CUDC-101, an HDAC, EGFR and Her2 inhibitor, in patients with locally advanced head and neck cancers and we also initiated a phase I dose escalation study of CUDC-101 oral tablet in patients with advanced and refractory solid tumors. We subsequently terminated the oral tablet study due to insufficient drug exposure observed in the first cohort of patients and we are currently assessing alternative oral formulations that may provide improved drug exposure for patients.
- We controlled costs and expenses in order to meet the above objectives within the parameters of our 2012 operating budget.

# Pay-for-Performance

In 2012 and to-date in 2013, the compensation committee adhered to its long-standing pay-for-performance philosophy. As such, a significant portion of total 2012 executive compensation was comprised of cash incentives and long-term compensation tied to corporate performance. The average base salary of our executive officers' comprised 32% of such executive officer's total compensation.

Key compensation decisions for 2012 and to-date in 2013 were as follows:

- In January 2012, the compensation committee increased base salary amounts for our executive officers as follows: (i) Mr. Passeri, from \$400,000 to \$450,000; (ii) Mr. Gray, from \$300,000 to \$350,000; (iii) Mr. Noel, from \$215,000 to \$225,000 and (iv) Dr. Voi, from \$375,000 to \$400,000.
- In January 2012, the compensation committee approved the 2012 short-term incentive plan. This plan was designed to motivate our executive officers to achieve specified performance objectives for fiscal year 2012 and to reward them for their achievement assuming those objectives were met. In January 2013, the compensation committee determined that it would award cash incentive payments to executive officers at 75% of target levels included within the 2012 short-term incentive plan based upon the company's performance during 2012, resulting in cash incentive awards to Messrs. Passeri, Gray and Noel and Dr. Voi of an aggregate of \$391,000.

• In January 2012, the compensation committee granted stock options to our executive officers. The purpose of these equity grants was to create an incentive for our executive officers to increase stockholder value over time through stock price growth, thereby aligning our executives' interests with those of our stockholders.

In 2012, our compensation committee also considered whether or not to implement stock ownership guidelines for our executive officers and directors. In September 2012, the compensation committee engaged Towers Watson to review the current stock ownership of our executive officers and directors as well as to review stock ownership practices of our peer group companies. Towers Watson analyzed the most recent proxy filings of the twenty peer group companies used in the September 2012 executive officer and director compensation analysis (for more information, see below under "Elements of Compensation and Analysis of Compensation Payments") to determine both the prevalence and design of executive stock ownership requirements. Of these twenty organizations, only two (or 10%) have adopted stock ownership guidelines. Towers Watson also noted that all of our executive officers except for Dr. Voi, who joined Curis in November 2011, would fulfill competitive market levels of ownership when both common shares owned outright and vested in-the-money stock options were counted towards the guidelines. Based on Towers Watson's findings, the compensation committee determined that it would continue to monitor the adoption of ownership policies among our peer group and the broader pre-commercial life sciences sector but would not presently recommend the implementation of stock ownership guidelines.

# **Our Compensation Program**

The primary objectives of the compensation committee with respect to executive officer compensation are to:

- attract and retain key executive officers critical to our long-term success;
- recognize and reward overall company performance and each executive officer's individual performance and level of responsibility; and
- align our executive officers' incentive compensation with stockholder interests.

To achieve these objectives, the compensation committee has previously set base salary and total cash compensation at approximately the 50th percentile and long-term incentive compensation at the 75th percentile of peer group company benchmarking data. In September 2010, our compensation committee retained Towers Watson to serve as an independent outside consultant reporting directly to the compensation committee with respect to executive and director compensation and stock ownership guidelines. Towers Watson was engaged to, among other things, conduct a benchmarking assessment of our executive officer compensation. Our compensation committee did not retain Towers Watson to analyze fiscal 2011 or fiscal 2012 compensation, since the compensation committee believed that peer group compensation levels were unlikely to have changed materially since December 2010. The results of the 2010 benchmarking assessment were presented to our compensation committee and were utilized by our compensation committee in setting 2012 compensation for our executive officers. The benchmarking was based upon:

- comparative compensation data for 14 companies in our industry that were recommended in 2010 by Towers Watson and adopted by the compensation committee as appropriate peer companies based upon each company's financial profile, state of development and oncology focus; and
- a review of executive officer compensation data for companies in the 2010 Radford Global Life Sciences Compensation Survey with a headcount of less than 50 employees.

The peer group companies were as follows:

Antigenics, Inc.
Arqule, Inc.
AVEO Pharmaceuticals, Inc.
Celldex Therapeutics, Inc.
Idera Pharmaceuticals, Inc.
Immunomedics Inc.
Infinity Pharmaceuticals, Inc.

Keryx Biopharmaceuticals Inc.
Oxigene, Inc.
Pharmacyclics, Inc.
Sunesis Pharmaceuticals, Inc.
Telix, Inc.
Threshold Pharmaceuticals, Inc.
ZIOPHARM Oncology, Inc.

The elements of compensation included in the benchmarking assessment consisted of base salary, short-term annual incentive compensation opportunities, total cash compensation, the fair value of long-term incentive awards and actual total direct compensation for each of our executive officers as compared to the peer group companies. Towers Watson conducted a competitive analysis of compensation at the 25th, 50th and 75th percentiles of the benchmarking data.

In determining executive officer compensation, the compensation committee also considers the overall performance and financial condition of the company and each individual executive officer's performance in contributing to company performance. The compensation committee also considers the total number of shares available for future grant under our 2010 stock incentive plan when determining the size of stock awards to our executive officers. Our corporate goals and objectives are established through a process that involves input by our board and executive officers, including our chief executive officer. Management reports on progress towards the achievement of these goals during our periodic board of directors meetings. The compensation committee believes that aligning executive compensation with the successful achievement of these goals has the potential to create long-term value for our stockholders.

Our chief executive officer evaluates the performance of each of the other executive officers at least once annually against established company goals and objectives for such executive officer and also takes into consideration each executive officer's contribution to the achievement of company goals and objectives. These annual assessments are provided either orally or through a written periodic review. The chief executive officer provides recommendations to the compensation committee for all elements of compensation of our other executive officers based upon these evaluations, and the compensation committee considers our chief executive officer's assessments when determining compensation for our executive officers other than our chief executive officer. The compensation committee evaluates the performance of the chief executive officer based upon its assessment of the chief executive officer's performance, and this assessment is updated at periodic meetings as well as through recommendations from the chairman of our board of directors. Our chief executive officer does not participate in the determination of his own compensation.

In addition to its September 2012 stock ownership guidelines engagement, Towers Watson was also retained to review executive officer and director compensation. In February 2013, Towers Watson was retained to provide consulting services to our compensation committee regarding the design of our amended and restated 2010 stock incentive plan.

For a further discussion of the processes and procedures used by our compensation committee in considering and determining executive and director compensation, see "Executive and Director Compensation Processes" beginning on page 16 of this proxy statement.

# Elements of Compensation and Analysis of Compensation Payments

The elements of executive officer compensation vary from year to year and generally consist of the following:

- base salary;
- short-term cash incentives;
- · stock option and restricted stock awards;
- · insurance, retirement and other employee benefits; and
- change in control and severance benefits.

We do not have any formal policy or target for allocating compensation between long-term and short-term compensation, between cash and non-cash compensation or among the different forms of non-cash compensation. The compensation committee, after considering information including company performance, individual executive officer performance, the financial condition of the company, benchmarking data and other market compensation for executive officers at other similarly-sized oncology-focused companies, determines what it believes to be the appropriate level and mix of the various compensation components.

### Base Salary

Base salary is used to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our executive officers. Base salaries for our executive officers are established based on the scope of their responsibilities, periodically taking into account competitive market compensation paid by other companies for similar positions as well as the financial condition of the company. Base salaries are reviewed annually, and adjusted from time to time to reflect promotions and to realign salaries with market levels after taking into account individual responsibilities, performance and experience as well as the financial health of the company. The compensation committee generally believes that executive officer base salaries should approximate the 50th percentile of the range of salaries for executive officers in similar positions with similar responsibilities at comparable companies.

### 2012 Base Salaries

In January 2012, the compensation committee increased base salaries for our executive officers for fiscal year 2012 as follows:

Name	2012 Base Salary	2011 Base Salary
Daniel R. Passeri	T	\$400,000
Michael P. Gray	\$350,000 \$225,000	\$300,000 \$215,000
Mark W. Noel	\$400,000	. ,
Maurizio voi, W.D		•

The compensation committee decided to increase base salaries for Messrs. Passeri and Gray, due in part to the fact that the base salaries for these officers had remained unchanged since 2008 except for the period from October 2008 through October 2009 when Messrs. Passeri and Gray's base salaries were, at such officers' request, reduced by the compensation committee by \$100,000 and \$50,000, respectively, to aid in our efforts to conserve our cash as we worked to strengthen our business and financial position. Mr. Noel's base salary was

also reduced by \$21,000 in October 2008 and was adjusted in 2010 to \$215,000, an increase of \$5,000, or 2.4%, above the 2008 base salary level. The compensation committee also made these increases to the base salaries for Messrs. Passeri, Gray and Noel in recognition of the performance of these executive officers in leading Curis to meet a substantial portion of our key 2011 operating goals, our improved financial condition at January 2012 when compared to the start of the prior year, and our positive financial outlook for 2012, including FDA approval of Erivedge® in the U.S. and anticipated approval in Europe. The compensation committee also considered Towers Watson benchmarking data in determining the 2012 base salaries and concluded that the 2012 base salaries were within the compensation committee's compensation philosophy targets. The base salary for Dr. Voi was increased in order to better align his base salary with the base salary levels of our other executive officers.

#### 2013 Base Salaries

In September 2012, our compensation committee retained Towers Watson to serve as an independent outside consultant reporting directly to the compensation committee with respect to executive officer and director compensation and stock ownership guidelines. Towers Watson was engaged to, among other things, conduct a benchmarking assessment of our executive officer compensation. The results of this benchmarking assessment were presented to our compensation committee and were utilized by our compensation committee in setting 2013 compensation for our executive officers. The benchmarking was based upon:

- comparative compensation data for 20 companies in our industry that were recommended by Towers
  Watson and adopted by the compensation committee as appropriate peer companies based upon each
  company's financial profile, market capitalization, state of development and oncology focus; and
- a review of executive officer compensation data for companies in the 2012 Radford Global Life Sciences Compensation Survey with fewer than 50 employees.

The peer group companies were as follows:

Agenus Inc.
Arqule, Inc.
Astex Pharmaceuticals, Inc.
AVEO Pharmaceuticals, Inc.
BioCryst Pharmaceuticals, Inc.
Celldex Therapeutics, Inc.
Endocyte, Inc.
Enzon Pharmaceuticals Inc.
Geron Corporation
GTX Inc.

ImmunoGen, Inc.
Immunomedics Inc.
Infinity Pharmaceuticals, Inc.
Keryx Biopharmaceuticals Inc.
Merrimack Pharmaceuticals, Inc.
Sunesis Pharmaceuticals, Inc.
Synta Pharmaceuticals Corp.
Threshold Pharmaceuticals, Inc.
Verastem, Inc.
ZIOPHARM Oncology, Inc.

The elements of compensation included in the benchmarking assessment consisted of base salary, short-term annual incentive compensation opportunities, total cash compensation, the fair value of long-term incentive awards and actual total direct compensation for each of our executive officers as compared to the peer group companies. Towers Watson conducted a competitive analysis of compensation at the 25th, 50th and 75th percentiles of the benchmarking data. The benchmarking assessment showed that our executive officers' 2012 base salary and 2012 total cash compensation levels generally approximated the 50th percentile when compared to the peer group companies. Our executive officer base salaries and total cash compensation approximated the 75th percentile when compared to data within the 2012 Radford Global Life Sciences Compensation Survey with fewer than 50 employees. Long-term incentive compensation approximated the 75th percentile when

benchmarked against both the peer group companies and the Radford data. While the compensation committee considers both sources of data, it believes that the selected peer group data provides for the most accurate comparator since all companies in the peer group listing are publicly-held corporations with a median market capitalization at the time of analysis that approximates our market capitalization and each of these comparative companies is also focused in the development of oncology therapeutics.

Taking into consideration this benchmarking assessment, the compensation committee set base salary amounts for our executive officers for fiscal year 2013 as follows:

Name	2013 Base Salary	2012 Base Salary
	\$465,000	\$450,000
Daniel R. Passeri	4	
Michael P. Gray	\$360,000	\$350,000
Michael P. Gray	\$230,000	\$225,000
Mark W. Noel		,
Mark W. Noel	\$410,000	\$400,000

# Short-Term Cash Incentive Plans

Our compensation committee believes that allocating a meaningful amount of our executive officers' total cash compensation to the achievement of objectives under short-term incentive plans aligns our executive officers' interests with those of our stockholders. Accordingly, for both 2012 and 2013 our compensation committee implemented short-term incentive plans that set forth specific objectives that, if achieved, can result in short-term incentive cash compensation for our executive officers.

The cash incentive program is designed to motivate our executive officers to achieve specified performance objectives for the respective fiscal year and to reward them for their achievement assuming those objectives are met. To be eligible, an executive officer must (i) be designated by the compensation committee or independent board members, (ii) be serving as an executive officer at the time the award is paid and (iii) have achieved an overall performance evaluation at a "meets expectations" or higher level within our evaluation framework.

The compensation committee generally establishes categories of goals that are then further delineated into three levels of potential achievement: "Threshold;" "Target;" and "Maximum." Cash incentive payments may be paid based upon the degree to which each category of corporate goals has been achieved on this continuum, if at all. For each of the four categories, achievement of performance at the "Threshold" level results in a weighted payment of no less than 50% of the target amount, achievement of performance at the "Target" level results in a weighted payment equal to 100% of the target amount, and achievement of performance at the "Maximum" level results in a weighted payment of no more than 150% of the target amount.

The cash incentive program is administered by the compensation committee. The compensation committee has the authority and discretion to modify performance goals under the cash incentive program and has the right to amend, modify or terminate the cash incentive program at any time.

# 2012 Short-Term Cash Incentive Plan

The compensation committee approved the 2012 short-term cash incentive plan in February 2012. The compensation committee determined that the following executive officers were eligible to participate in the cash incentive program: Daniel R. Passeri, Michael P. Gray, Mark W. Noel and Maurizio Voi, M.D.

The compensation committee established the following target short-term incentive payment amounts, referred to herein as target amounts, for each executive officer:

Designated Executive Officer	esignated Executive Officer 2012 Annual Base Salary		Target Incentive Compensation Payment as a Percentage of 2012 Annual Base Salary, Assuming Performance at the 100% Level		
Daniel B. Besseri	<b>A</b> 4 <b>2 2 2 2 2 3 3 3 3 3 3 3 3 3 3</b>	(%)	(\$)		
Daniel R. Passeri	\$ 450,000	45%	\$202,500		
Michael P. Gray	\$ 350,000	35%	\$122,500		
Mark W. Noel	\$ 225,000	25%	\$ 56,250		
Maurizio Voi, M.D	\$ 400,000	35%	\$140,000		
Total	\$1,425,000	100%	\$521,250		

The compensation committee established four weighted categories of corporate goals for 2012. The four categories of corporate goals for 2012 generally relate to the following:

- the establishment of the maximum tolerated dose of CUDC-101, our lead candidate from our targeted cancer programs, in combination with cisplatin, a chemotherapeutic drug, and radiation in our ongoing phase I clinical trial in locally advanced head and neck cancer patients, and achievement of clinical trial enrollment;
- progress in preclinical efforts on an oral formulation of CUDC-101, including filing an IND and commencing treatment of patients;
- progress in preclinical efforts on CUDC-907, a development candidate from our targeted cancer programs, including filing an IND and commencing treatment of patients; and
- financial performance objectives, including cash management and capital objectives.

On January 17, 2013, the compensation committee approved the payment of short term cash incentive awards at 75% of the target amounts to each of the named executive officers as follows:

<u>Name</u>	Total 2012 Cash Incentive Amount Paid	Percentage of 2012 Base Salary
Daniel R. Passeri	\$151,875	34%
Michael P. Gray	\$ 91,875	26%
Mark W. Noel	\$ 42,188	19%
Maurizio Voi, M.D.	\$105,000	26%

# 2013 Short-Term Cash Incentive Plan

In January 2013, the compensation committee approved a 2013 short-term cash incentive program for executive officers and determined that the following executive officers were eligible to participate: Daniel R. Passeri, Michael P. Gray, Mark W. Noel and Maurizio Voi, M.D.

The compensation committee established the following target short-term incentive payment amounts, referred to herein as target amounts, for each executive officer:

Designated Executive Officer	2013 Annual Base Salary	Target Incentive Compensation Payment as a Percentage of 2013 Annual Base Salary, Assuming Performance at the 100% Level			
		(%)	(\$)		
Daniel R. Passeri	\$ 465,000	45%	\$209,250		
Michael P. Gray	\$ 360,000	35%	\$126,000		
Mark W. Noel	\$ 230,000	25%	\$ 57,500		
Maurizio Voi, M.D	\$ 410,000	35%	\$143,500		
Total	\$1,465,000	100%	\$536,250		

The compensation committee established four weighted categories of corporate goals for 2013. The four categories of corporate goals for 2013 generally relate to the following:

- the initiation and progression of clinical trials of CUDC-427;
- the completion of enrollment in the dose escalation portion of our phase I single agent study of CUDC-907 in hematological malignancies by the end of 2013 and the initiation of a phase I dose escalation combination study of CUDC-907 in solid tumors in the second half of 2013;
- the establishment of the maximum tolerated dose of and completion of clinical trial enrollment of our
  ongoing phase I clinical trial of CUDC-101 in locally advanced head and neck cancer patients in
  combination with cisplatin and radiation as well as the progression of preclinical efforts to establish a
  suitable oral formulation of CUDC-101; and
- financial performance objectives, including cash management and capital objectives.

The awards, if any, generally will be paid in cash. The compensation committee has sole discretion, however, to pay an award using a combination of cash and equity or all equity, with any such equity being issued pursuant to our 2010 stock incentive plan. If the compensation committee determines that such payment will be made in whole or in part in the form of equity, the compensation committee shall have the sole discretion, subject to the terms of the 2013 short-term cash incentive program generally, to determine the nature, amount and other terms of such equity award. Payment of the awards, if any, will be made after the completion of fiscal year 2013 and no later than March 15, 2014.

In the event of the consummation of a change in control of the company on or before December 31, 2013, short-term incentive amounts shall be paid out at 100% of the target amount upon such change in control.

### Long-Term Incentive Program

The compensation committee believes that long-term value creation is achieved through an ownership culture that encourages performance by our executive officers through stock and stock-based awards. We have established our stock compensation plans to provide our employees, including our executive officers, with incentives to help align employee interests with the interests of our stockholders. The exercisability of stock options and the vesting of restricted stock awards are generally time-based. All the value received by the recipient from a stock option is based on the growth of the stock price above the option exercise price. Our executive officers have historically paid the par value of \$0.01 per share of common stock for restricted stock awards. Accordingly, the value received by the recipient for a restricted stock award is equal to the difference

between the fair market value of our common stock on the date the restricted stock award is granted and the \$0.01 per share paid for such restricted stock, plus any future growth of the stock price after such grant date.

# Stock Options

Our 2010 stock incentive plan permits the grant of incentive and non-qualified stock options to our employees, directors and consultants. In the first quarter of 2010, our 2000 stock incentive plan expired in accordance with its terms and our 2000 director stock option plan had no available shares remaining. 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 compensation committee reviews and approves stock option grants to our chief executive officer and the other executive officers. Stock option grants are made at the commencement of employment and then are generally granted annually in conjunction with the review of the individual performance of our executive officers. Grants may also be made following a significant change in job responsibilities or to meet other special retention or performance objectives. The review and approval of stock option awards to executive officers is based upon an assessment of individual performance, a review of each executive officer's existing long-term incentives and retention considerations. In appropriate circumstances, the compensation committee considers the recommendations of Mr. Passeri, our chief executive officer (except with respect to his own compensation) and Mr. McNab, the chairman of our board of directors. Stock options are typically granted with an exercise price equal to the fair market value of our common stock on the date of grant and typically vest and become exercisable as to 25% of the shares underlying the award after the first year and as to an additional 6.25% of the shares underlying the award in each subsequent quarter, based upon continued employment over a four-year period. The options generally expire ten years after the date of grant. In certain circumstances, stock options have and may be granted with different vesting terms, such as a shorter vesting period or performance-based vesting.

### 2012 Stock Option Grants

In January 2012, the compensation committee granted the following stock options pursuant to our 2010 stock incentive plan to our executive officers:

Name	Number of Shares Underlying January 2012 Option Grants
Daniel R. Passeri	400,000
Michael P. Gray	250,000
Mark W. Noel	80,000
Maurizio Voi, M.D. (1)	100,000

<sup>(1)</sup> Dr. Voi has served as our executive vice president, chief medical and development officer since November 7, 2011 and was granted an option to purchase 350,000 shares of common stock at the time of his hiring. That option vests over four years, 25% after the first year and 6.25% per quarter over the remainder of the vesting period.

The compensation committee believes that targeting the 75th percentile of our peer group is consistent with its desire to emphasize equity opportunity, align executive officer and stockholder interests and manage our cash consumption. In determining the size of each stock option grant awarded to our named executive officers in 2012, the compensation committee targeted the 75th percentile of value for the peer group established by Towers

Watson in 2010, data from the related Radford Global Life Sciences Compensation Survey for long-term incentive compensation, as well the compensation committee's desire to preserve adequate common shares for future stock options and other stock awards that may be granted under the 2010 stock incentive plan. The value of the stock option awards granted to our executive officers was moderately greater than the 75th percentile from the 2010 peer group data, which included data for stock option awards that were made in 2009. The value of the 2012 awards is approximately equal to the 75th percentile from the September 2012 Towers Watson peer group data, which includes stock options granted from our current peer group in 2011. The compensation committee increased stock option awards in 2012, particularly to Mr. Passeri and Mr. Gray in part because of the contributions made by these officers during 2011 in advancing our primary 2011 operating goals as well as the fact that the 2011 awards were much lower than the compensation committee's 75th percentile target.

### 2013 Stock Option Grants

In January 2013, the compensation committee granted the following stock options pursuant to our 2010 stock incentive plan to our executive officers:

Name	Number of Shares Underlying January 2013 Option Grants	Percentage Increase/ (Decrease) from Prior Year Grants
Daniel R. Passeri	200,000	(50%)
Michael P. Gray	125,000	(50%)
Mark W. Noel	60,000	(25%)
Maurizio Voi, M.D.	125,000	25%

The number of shares awarded to our executive officers in January 2013 was equal to the number of shares awarded in 2011. The 2013 awards decreased as compared to our 2012 grants, both in absolute numbers and in the underlying value at the time of grant. The value of the stock option awards granted to our executive officers in 2013 was between the 25th and 50th percentiles when compared to the September 2012 Towers Watson peer group data. In setting the number of shares to our executive officers in January 2013 at levels below the 75th percentile, the compensation committee considered the number of shares currently available for future grant under the 2010 stock incentive plan. The compensation committee also considered data within the Towers Watson's 2012 report that noted that over 60% of organizations utilize a fixed share approach to their annual equity awards.

# Restricted Stock Awards

Our 2010 stock incentive plan permits the issuance of restricted stock awards to our employees, directors and consultants. The compensation committee generally does not make grants of restricted stock awards to our executive officers and no restricted stock awards were granted in 2012. The compensation committee generally favors the award of stock options over restricted stock in its annual compensation of our executive officers since it grants stock options with exercise prices that are equal to the fair market value of our common stock on the grant date, and therefore closely aligns our executive officers' interests with those of our stockholders as such stock options only generate value to our executive officers if the fair market value of our common stock rises.

#### Other 2013 Compensation Awards

In February 2013, Dr. Ali Fattaey was appointed our president and chief operating officer. In connection with his appointment, Dr. Fattaey's annualized base salary for 2013 was fixed at \$425,000 and he is eligible to

receive an annual bonus of up to 40% of his base salary, based on the attainment of specified performance targets established by the compensation committee. In addition, the compensation committee determined that Dr. Fattaey is eligible to participate in the 2013 cash incentive program and it granted Dr. Fattaey an option to purchase 400,000 shares of our common stock. This stock option has a ten-year term, vests as to 25% of the shares underlying the grant on the first anniversary of his date of hire and as to the remaining shares underlying the option in equal quarterly installments thereafter, subject to his continued service, and has an exercise price equal to the closing price of a share of our common stock on the NASDAQ Global Market on the date of grant. In establishing this compensation package for Dr. Fattaey, the compensation committee considered the relative compensation of our other executive officers and Towers Watson benchmarking data for his role as our president and chief operating officer.

### 2010 Employee Stock Purchase Plan

Executive officers are eligible to participate in our 2010 employee stock purchase plan. The plan permits participant employees to purchase company stock through payroll deductions of up to 15% of total cash compensation. The price of the stock is 85% of the lower of the fair market value of the stock at the beginning or the end of the offering period. In 2012, none of our executive officers participated in the 2010 employee stock purchase plan.

### Other Compensation - Employee Benefits

Our employees, including our executive officers, are entitled to various employee benefits such as medical and dental expense coverage, flexible spending accounts, various insurance programs, an employee assistance program and paid time off. Executive officers are eligible to participate in our 401(k) retirement plan. Matching contributions to the 401(k) plan are at the discretion of the compensation committee of the board of directors.

### Change in Control and Severance Payments

Each of our executive officers is party to an agreement or offer letter that obligates us to make payments to such executive officer in the event we terminate the executive officer's employment without cause or the executive officer resigns for good reason (as defined in the applicable agreement or offer letter). We believe that our severance program is aligned with other comparable biotechnology companies and provides our executive officers with income protection in the event of an unplanned separation from employment. In addition, we are also obligated to make payments to each of our executive officers if he is terminated under specified circumstances within twelve months after a change in control. This is a so-called "double trigger" change in control arrangement because it provides for severance benefits only in the event of a change in control, the first trigger, followed by an employment termination under specified circumstances, the second trigger. Our 2000 and 2010 stock incentive plans provide that all plan participants, including our executive officers, are entitled to accelerated vesting of stock options and/or restricted stock awards upon certain events. In the event that a change in control occurs, 50% of the then unvested options of each plan participant, including executive officers, would become immediately exercisable and the restrictions underlying 50% of any restricted stock awards would lapse. In the event any executive officer is terminated within one year after a change in control without cause or resigns for good reason (each as defined in the applicable plan), then all remaining unvested stock options and restricted stock awards will become fully vested. Our 2000 and 2010 stock incentive plans generally define a change in control as a merger by us with or into another company or a sale of all or substantially all of our assets. We have determined to provide for these change in control arrangements because we recognize that, as is the case with

many publicly-held corporations, the possibility of a change in control of our company exists and such possibility, and the uncertainty and questions which it may raise among our executive officers, could result in the departure or distraction of executive officers to the detriment of our company and our stockholders. As a consequence, our compensation committee determined to provide such change in control related benefits to reinforce and encourage the continued employment and dedication of our executive officers without distraction from the possibility of a change in control and related events and circumstances.

Our change in control and severance arrangements with our executive officers do not obligate us to make any additional payments to "gross-up" any such compensation payable to such executive officers in order to offset income tax liabilities.

For a further description of the foregoing arrangements, see "Summary Compensation Table," "Employment Agreements" and "Potential Payments Upon Termination or Change in Control."

# **Tax and Accounting Considerations**

We account for equity compensation paid to our employees under the rules of FASB Codification Topic 718 (formerly FAS 123(R)), which require us to estimate and record an expense over the service period of the award. Accounting rules also require us to record cash compensation as an expense at the time the obligation is accrued. To date, these accounting requirements have not impacted our executive compensation programs and practices.

The Internal Revenue Service, pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, generally disallows a tax deduction for compensation in excess of \$1.0 million paid to our chief executive officer and to each other officer (other than our chief executive officer and our chief financial officer) whose compensation is required to be reported to our stockholders pursuant to the Exchange Act by reason of being among the three most highly paid executive officers. Certain compensation, including qualified performance-based compensation, will not be subject to the deduction limit if certain requirements are met. The compensation committee reviews the potential effect of Section 162(m) periodically and uses its judgment to authorize compensation payments that may be subject to the limit when the compensation committee believes that such payments are appropriate and in the best interests of us and our stockholders, after taking into consideration changing business conditions and the performance of our employees.

# **Summary Compensation Table**

The following table sets forth information regarding compensation earned by each of our named executive officers for the fiscal years ending December 31, 2012, 2011, and 2010.

Name and Principal Position	Year	Salary (\$)	Bonus (\$) (1)	Stock Awards (\$)	Option Awards (\$) (2)	All Other Compensation (\$)	Total (\$)
Daniel R. Passeri	2012	450,000	151.875		1,194,680	10,000(3)	\$1,806,555
Chief Executive	2011	400.000	150,000		281,440	9,800(3)	841,240
Officer	2010	391,923	200,000		577,155	7,350(3)	1,176,428
Michael P. Gray	2012	350,000	91,875		746,675	10,000(3)	1,198,550
Chief Financial	2011	300,000	125,000		175,900	9,800(3)	610,700
Officer	2010	295,961	166,667		353,503	7,350(3)	823,481
Mark W. Noel	2012	225,000	42,188	·	238,936	9,000(3)	515,124
Vice President,	2011	215,000	50,000		84,432	8,600(3)	358,032
Technology	2010		66,667		158,708	6,387(3)	444,662
Management and Intellectual Property		ŕ					
Maurizio Voi, M.D. (4)	2012	400,000	105,000		298,670	80,661(3)(5	) 884,331
Executive Vice President, Chief Medical Officer and Chief Development	2011	57,692	26,000	_	869,540	692(3)	953,924
Officer							

- (1) Consists of bonuses approved by the compensation committee and accrued in our financial statements at December 31, 2012, 2011 and 2010. All of the 2012 bonuses earned were not paid until January 2013. All of the 2011 bonuses earned were not paid until January 2012, and a portion of each officer's bonus earned in 2010, \$158,333 in the aggregate, was not paid until January 2011.
- (2) The amounts in this column reflect the aggregate grant date fair value of equity awards granted during the respective fiscal year, computed in accordance with FASB Codification Topic 718 and other relevant guidance, for awards pursuant to our 2000 and 2010 stock incentive plans. Assumptions used in the calculation of these amounts are included in footnote 5 to our audited financial statements for the fiscal year ended December 31, 2012 included in our Annual Report on Form 10-K filed with the SEC on March 13, 2013. During 2007, our named executive officers were issued certain options, the exercisability of which was tied to a performance condition, the occurrence of which was not probable at the date of grant. The related performance conditions were met in 2010. The following table denotes the maximum value of these 2007 options which are included in the Summary Compensation Table:

Name	2007 Performance Condition Options
Daniel R. Passeri	\$288,775
Michael P. Gray	173,265
Mark W. Noel	72,194

<sup>(3)</sup> Consists of 401(k) contributions made by us.

<sup>(4)</sup> Dr. Voi has served as our executive vice president, chief medical and development officer since November 7, 2011, and his 2011 salary reflects the amount earned from this date through December 31, 2011.

<sup>(5)</sup> Of this amount, \$70,661 represents reimbursed relocation expenses for Dr. Voi in 2012.

#### **Grants of Plan-Based Awards**

The following table sets forth information regarding awards under our 2010 stock incentive plan to our named executive officers during the fiscal year ended December 31, 2012.

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)(1)	Exercise or Base Price of Option Awards (\$/Sh)(2)	Grant Date Fair Value of Stock and Option Awards (3)
Daniel R. Passeri	01/5/2012	400,000	\$4.52	\$1,194,680
Michael P. Gray	01/5/2012	250,000	4.52	746,675
Mark W. Noel	01/5/2012	80,000	4.52	238,936
Maurizio Voi, M.D	01/5/2012	100,000	4.52	298,670

- (1) Such stock options will expire 10 years from date of grant. These stock options vest over a period of four years with 25% of the shares underlying the grant vesting on January 5, 2013 and an additional 6.25% of the shares underlying the grant vesting at the end of each successive three-month period until the option is fully vested on the fourth anniversary of the grant date, subject to the continued employment of the executive officer. In the event of a change in control, 50% of the then unvested options held by each plan participant, including executive officers, would become immediately exercisable. Under the terms of the 2010 stock incentive plan, a change in control generally occurs in the event we merge with or into another company or we sell all or substantially all of our assets. In addition, under the terms of the 2010 stock incentive plan, in the event an executive officer terminates his employment for good reason (as defined in the plan) or we terminate the executive officer without cause (as defined in the plan) within one year after a change in control, then all options held by the executive officer would become fully vested upon such termination.
- (2) The exercise price per share is equal to the closing price per share of our common stock on the date of grant.
- (3) The amounts shown in this column represent the total grant date fair value of each stock and option award as determined in accordance with FASB Codification Topic 718.

### Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table

We have entered into employment agreements with our named executive officers, as described below under "Employment Agreements" and "Indemnification of Executive Officers."

Salary and bonus payments accounted for approximately 41.2% of the total compensation of the named executive officers for 2012, 68.1% of the total compensation of the named executive officers for 2011 and 56.7% of the total compensation of the named executive officers for 2010.

# **Outstanding Equity Awards at Fiscal Year-End**

The following table summarizes the outstanding equity awards held by our named executive officers as of December 31, 2012.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) (1) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Daniel R. Passeri		400,000	\$4.52	1/05/2022
Dunier IX. I doseit	87,500	112,500	\$2.15	1/07/2021
	137,500	62,500	\$2.27	2/02/2020
	281,250	18,750	\$1.07	2/05/2019
	202,000		\$0.79	10/24/2018
	300,000	_	\$1.43	1/25/2018
	500,000		\$1.39	6/06/2017
	390,000	<del></del>	\$1.57	5/31/2016
	175,000		\$3.98	6/01/2015
	175,000		\$4.56	6/25/2014
	450,000		\$2.43	5/13/2013
Michael P. Gray	_	250,000	\$4.52	1/05/2022
•	54,687	70,313	\$2.15	1/07/2021
	85,935	39,064	\$2.27	2/02/2020
	168,750	11,250	\$1.07	2/05/2019
	180,000	·	\$1.43	1/25/2018
	300,000	_	\$1.39	6/06/2017
	200,000	_	\$1.57	5/31/2016
	75,000		\$3.98	6/01/2015
	75,000		\$4.56	6/25/2014
	160,000		\$4.95	12/11/2013
	50,000		\$2.43	5/13/2013
Mark W. Noel	·	80,000	\$4.52	1/05/2022
	26,250	33,750	\$2.15	1/07/2021
	41,249	18,751	\$2.27	2/02/2020
	70,312	4,688	\$1.07	2/05/2019
	43,000		\$0.79	10/24/2018
	75,000		\$1.43	1/25/2018
	125,000		\$1.39	6/06/2017
	100,000		\$1.57	5/31/2016
	50,000	_	\$3.98	6/01/2015
	50,000	<del></del>	\$4.56	6/25/2014
	70,000		\$2.43	5/13/2013
Maurizio Voi, M.D		100,000	\$4.52	1/05/2022
	87,500	262,500	\$3.76	11/08/2021

<sup>(1)</sup> Such stock options will expire 10 years from date of grant. These stock options vest over a period of four years with 25% of the shares underlying the grant vesting on the first anniversary of the grant date and an additional 6.25% of the shares underlying the grant vesting at the end of each successive three-month period until the option is fully vested on the fourth anniversary of the grant date, subject to the continued

employment of the executive officer. In the event of a change in control, 50% of the then unvested options held by each plan participant, including executive officers, would become immediately exercisable. Under the terms of the 2000 and 2010 stock incentive plans, a change in control generally occurs in the event we merge with or into another company or we sell all or substantially all of our assets. In addition, under the terms of the 2000 and 2010 stock incentive plans, in the event an executive officer terminates his employment for good reason (as defined in the plan) or we terminate the executive officer without cause (as defined in the plan) within one year after a change in control, then all options held by the executive officer would become fully vested upon such termination.

## **Option Exercises**

The following table summarizes, for each of our named executive officers, each exercise of stock options during 2012.

	Option Awards			
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)		
Daniel R. Passeri	77,563	248,600		
Michael P. Gray	67,425	225,843		
Mark W. Noel	122,100	399,276		
Maurizio Voi. M.D.	·	,		

## **Employment Agreements**

We are party to the following employment arrangements with our executive officers.

Daniel R. Passeri. On September 18, 2007, we entered into an employment agreement with Mr. Passeri. The agreement, as amended on October 27, 2008, December 10, 2010 and January 18, 2013, is intended to comply with the applicable provisions of Section 409A of the Internal Revenue Code of 1986, as amended, and the final Treasury regulations and guidance issued thereunder. The agreement provided that Mr. Passeri would serve as our president and chief executive officer for the period that commenced on September 18, 2007 and ends on December 31, 2013. On February 18, 2013, Ali Fattaey, Ph.D. assumed the role of president and chief operating officer and Mr. Passeri remains as our chief executive officer. Mr. Passeri's current base salary, which is subject to annual review by the board, is \$465,000. Mr. Passeri's agreement also provides for the payment of Mr. Passeri's fees for preparation of his tax return by a tax professional. Mr. Passeri is entitled to participate in our medical and other benefit programs and may be entitled to receive an annual bonus based on the achievement of specific objectives established by the board. Mr. Passeri is also entitled to receive severance benefits under the agreement in the event of his termination without cause or for good reason (as defined in the agreement) and he is also entitled to receive certain payments if he is terminated within one year after a change in control. For a description and quantification of such severance and change in control benefits, see "Potential Payments Upon Termination or Change In Control." In addition, the agreement provides for certain indemnification provisions. For a description of such indemnification provisions, see "Indemnification of Executive Officers."

Michael P. Gray. On December 15, 2003, we entered into an employment agreement with Mr. Gray. The agreement, as amended on October 31, 2006, October 27, 2008 and December 10, 2010, is intended to comply with the applicable provisions of Section 409A of the Internal Revenue Code of 1986, as amended, and the final Treasury regulations and guidance issued thereunder. Mr. Gray's current base salary, which is subject to review as part of our performance review program is \$360,000. Mr. Gray is entitled to participate in our medical and

other benefit programs and may be entitled to receive an annual bonus based on the achievement of specific objectives established by the board. Mr. Gray is also entitled to receive severance benefits under the agreement in the event of his termination without cause or for good reason (as defined in the agreement) and he is also entitled to receive certain payments if he is terminated within one year after a change in control. For a description and quantification of such severance and change in control benefits, see "Potential Payments Upon Termination or Change In Control." In addition, the agreement provides for certain indemnification provisions. For a description of such indemnification provisions, see "Indemnification of Executive Officers."

Mark W. Noel. On January 11, 2001, we entered into an employment agreement with Mr. Noel. The agreement, as amended on October 31, 2006, October 27, 2008 and December 10, 2010, is intended to comply with the applicable provisions of Section 409A of the Internal Revenue Code of 1986, as amended, and the final Treasury regulations and guidance issued thereunder. Mr. Noel's current base salary, which is subject to review as part of our performance review program, is \$230,000. Mr. Noel is entitled to participate in our medical and other benefit programs and may be entitled to receive an annual bonus based on the achievement of specific objectives established by the board. Mr. Noel is also entitled to receive severance benefits under the agreement in the event of his termination without cause or for good reason (as defined in the agreement) and he is also entitled to receive certain payments if he is terminated within one year after a change in control. For a description and quantification of such severance and change in control benefits, see "Potential Payments Upon Termination or Change In Control." In addition, the agreement provides for certain indemnification provisions. For a description of such indemnification provisions, see "Indemnification of Executive Officers."

Maurizio Voi, M.D. On November 7, 2011, we entered into an employment agreement with Dr. Voi. The agreement is intended to comply with the applicable provisions of Section 409A of the Internal Revenue Code of 1986, as amended, and the final Treasury regulations and guidance issued thereunder. Under the agreement, Dr. Voi will serve as our executive vice president, chief medical officer and chief development officer for the period that commenced on November 7, 2011 and ends on November 7, 2015. Dr. Voi's current base salary, which is subject to review as part of our performance review program, is \$410,000. Dr. Voi is entitled to participate in our medical and other benefit programs, received reimbursement in the amount of \$70,661 related to his relocation and may be entitled to receive an annual bonus based on the achievement of specific objectives established by the board. Dr. Voi is also entitled to receive severance benefits under the agreement in the event of his termination without cause or for good reason (as defined in the agreement) and he is also entitled to receive certain payments if he is terminated within one year after a change in control. For a description and quantification of such severance and change in control benefits, see "Potential Payments Upon Termination or Change In Control." In addition, the agreement provides for certain indemnification provisions. For a description of such indemnification provisions, see "Indemnification of Executive Officers."

### **Indemnification of Executive Officers**

Our certificate of incorporation provides indemnification of our executive officers for any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action or claim by or in the right of the company) by reason of the fact that such person serves as an executive officer, to the maximum extent permitted by the General Corporation Law of Delaware. The certificate of incorporation further provides that executive officers may be entitled to additional indemnification, under any agreement or vote of the directors.

Each of our executive officer employment agreements also provides that we will indemnify each such executive officer for claims arising in his capacity as our executive officer, provided that he acted in good faith

and in a manner that he reasonably believed to be in, or not opposed to, our best interests. With respect to any criminal proceeding, the executive officer must have no reasonable cause to believe that the conduct was unlawful. If the claim is brought by us or on our behalf, we will not be obligated to indemnify the executive officer if the executive officer is found liable to us, unless the court determines that, despite the adjudication of liability, in view of all the circumstances of the case the executive officer is fairly and reasonably entitled to be indemnified. In the event that we do not assume the defense of a claim against the executive officer, we are required to advance his expenses in connection with his defense, provided that he undertakes to repay all amounts advanced if it is ultimately determined that he is not entitled to be indemnified by us. We will require that any successor to our business assumes and agrees to perform our obligations under the indemnification provisions.

In connection with our indemnification obligations we have and intend to maintain director and officer liability insurance, if available.

# Potential Payments Upon Termination or Change in Control

Each of the above-described employment agreements with our executive officers provides that in the event we terminate the executive officer's employment without cause or if the executive officer resigns for good reason (each as defined in the agreements) including a termination within twelve months after a change in control of the company, the executive officer will receive: (1) his base salary (as defined in the agreement) accrued through the last day of employment; (2) continuation of his then base salary or a portion thereof for the periods and amounts described in the table below, and (3) payment of a portion of the executive officer's COBRA premiums, which is calculated as the difference between the COBRA premium and the amount paid by the employee for medical/dental insurance, for the periods and amounts described in the table below. In order for our executive officers to receive these severance payments, the executive officer must execute a general release of all claims against the company, its employees, officers, directors and agents in a form acceptable to us.

If either of Messrs. Gray or Noel is considered a "specified employee" on the date of his termination within the meaning of Section 409A(a)(2)(B)(i) of the Internal Revenue Code and the regulations thereunder, and any payments to be paid or provided to such executive officer constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended, then the severance and benefit payments per the table below will be delayed by a period of six months and will be paid in a lump sum in the seventh month following the date of termination. If either Mr. Passeri or Dr. Voi is considered a "specified employee" on the date of his termination, then his severance and benefit payments will be paid within the short-term deferral period, which means the period ending on the later of the 15th day of the third month following the end of the employee's separation from service occurs and the 15th day of the third month following the end of our tax year in which such employee's separation from service occurs, and shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A of the Code. If Mr. Passeri's or Dr. Voi's severance and benefit payments are not paid within the short-term deferral period then such payments will be delayed by a period of six months and will be paid in a lump sum in the seventh month following the date of termination.

Pursuant to the terms of our 2000 and 2010 stock incentive plans, at the time of a change in control, 50% of the then-unvested options to purchase our common stock held by each plan participant, including executive officers, would become immediately exercisable and the forfeiture restriction on all outstanding restricted stock awards would lapse with respect to 50% of the number of shares that otherwise would have first become free from such forfeiture restrictions after the date of the change in control. In addition, in the event an executive

 $\mathcal{T}_{\mathcal{A}}$  , where  $\mathcal{T}_{\mathcal{A}}$  is the substitution of the su

officer terminates his employment for good reason (as defined in the applicable plan) or we terminate the executive officer without cause (as defined in the applicable plan) within one year after such change in control, then all remaining unvested options and restricted stock held by the executive officer would become fully vested and/or free of all forfeiture restrictions, as applicable.

The table below sets forth the estimated benefits provided to each of our named executive officers upon a termination event described above, assuming such termination event occurred on December 31, 2012, the last day of our most recently completed fiscal year.

Name	Severance Term in Months	Severance Upon Termination (\$)	Value of Equity Acceleration (1)	Benefits Upon Termination (\$)	Total Benefits
Daniel R. Passeri	Twelve	\$450,000	\$130,375	\$13,350	\$593,725
Michael P. Gray Chief Financial Officer	Six	\$175,000	\$ 80,932	\$ 6,675	\$262,607
Mark W. Noel Vice President Technology Management and Intellectual Property	Six	\$112,500	\$ 38,007	\$ 6,675	\$157,182
Maurizio Voi, M.D	Six	\$200,000	\$ <b>-</b>	\$ 6,737	\$206,737

<sup>(1)</sup> Represents the value of that portion of each named executive officer's in-the-money stock options that would accelerate upon a change in control, assuming such change in control occurred on December 31, 2012, after deducting the exercise price and based upon the \$3.43 closing price of our common stock on the Nasdaq Global Market on December 31, 2012. As noted above, pursuant to the terms of our stock incentive plans, at the time of a change in control, 50% of the then-unvested options become immediately exercisable. In addition, in the event an executive officer terminates his employment for good reason (as defined in the applicable plan) or we terminate the executive officer without cause (as defined in the applicable plan) within one year after such change in control, then all remaining unvested options held by the executive officer would become fully vested and/or free of all forfeiture restrictions, as applicable. Assuming that such termination was to occur within one year after a change of control, the total value of accelerated in-themoney stock options would be as follows: Mr. Passeri, \$260,750; Mr. Gray, \$161,865; Mr. Noel, \$76,015; and Dr. Voi, \$0.

### **Director Compensation Table**

The following table sets forth a summary of the compensation earned by or paid to our non-employee directors in 2012:

Name	Fees Earned or Paid In Cash(\$)	Option Awards (\$) (1) (2)	All Other Compensation (\$)	Total (\$)
Susan B. Bayh	\$ 29,250	\$149,330	\$	\$178,580
Martyn D. Greenacre	40,750	149,330	<u> </u>	190,080
Kenneth I. Kaitin, Ph.D.	31,250	149,330	·	180,580
Robert E. Martell, M.D., Ph.D.	26,250	149,330	-	175,580
James R. McNab, Jr		507,722	24,241(4)	677,713
Marc Rubin, M.D.	27,000	149,330		176,330
James R. Tobin	31,250	149,330		180,580

<sup>(1)</sup> The amounts in this column reflect the grant date fair value of awards made to such individual in accordance with FASB Codification Topic 718 and other relevant guidance, excluding forfeitures, for awards in 2012 pursuant to our 2010 stock incentive plan. Assumptions used in the calculation of these amounts are included in footnote 5 to our audited financial statements for the fiscal year ended December 31, 2012 included in our Annual Report on Form 10-K filed with the SEC on March 13, 2013.

(2) At December 31, 2012, each of our current non-employee directors held options to purchase shares of our common stock as follows:

<u>Director</u>	Aggregate Number of Stock Options
Susan B. Bayh	309,045
Martyn D. Greenacre	320,000
Kenneth I. Kaitin, Ph.D.	215,000
Robert E. Martell, M.D., Ph.D.	75.000
James R. McNab, Jr.	210,000
Marc Rubin, M.D.	100,000
James R. Tobin	197,500

<sup>(3)</sup> On June 1, 2005, we entered into an agreement with Mr. McNab relating to his service as chairman of the board of directors. As chairman of the board of directors, Mr. McNab receives a cash payment of \$10,000 per month plus board attendance fees.

(4) Consists of payments made by us to reimburse the cost of Mr. McNab's annual health insurance expense.

Non-employee directors receive an initial stock option grant upon election to the board and annual stock option grants upon reelection to the board. In addition, non-employee directors, other than Mr. McNab, receive an annual cash retainer of \$15,000. Mr. McNab receives an annual cash retainer of \$120,000. Non-employee directors who serve as committee chairpersons of the nominating and corporate governance committee or of the compensation committee receive an additional \$5,000 payment for such committee chairperson services. Non-employee directors who serve as the committee chairperson of the audit committee receive an additional payment of \$10,000 for such committee chairperson services. Directors are paid additional cash compensation in the amount of \$1,500 for each board or committee meeting attended in person and \$750 for telephonic meetings. In

addition, directors are reimbursed for reasonable out-of-pocket expenses that are incurred due to attendance at board or committee meetings. Directors who are our employees are not compensated for their attendance at board or committee meetings.

On March 7, 2013, our board of directors elected Kenneth J. Pienta, M.D., to serve as a class I director. Dr. Pienta will receive compensation for his board service as a non-employee director commensurate with our director compensation program, including a one-time nonqualified stock option under the 2010 stock incentive plan to purchase 25,000 shares of our common stock with an exercise price equal to the closing price of our common stock on the grant date. Dr. Pienta receives compensation in the amount of \$50,000 per year for his services as a member and chairman of our scientific advisory board. In addition, Dr. Pienta served as a consultant to the company under which we agreed to pay Dr. Pienta \$10,000 per month. We and Dr. Pienta terminated the consulting agreement in connection with his election as a member of the board of directors. Since January 1, 2012, Dr. Pienta has received aggregate payments from the company of \$142,258 related to these two relationships.

# **Indemnification of Directors**

Our certificate of incorporation provides indemnification of our directors for any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action or claim by or in the right of the company) by reason of the fact of that such person serves as a director, to the maximum extent permitted by the General Corporation Law of Delaware. The certificate of incorporation further provides that directors may be entitled to additional indemnification, under any agreement or vote of the directors.

We have entered into indemnification agreements with each of our non-employee directors. The indemnification provisions apply to each such director and state that we will indemnify him or her for claims arising in his or her capacity as our director, provided that he or she acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, our best interests. With respect to any criminal proceeding, the director must have no reasonable cause to believe that the conduct was unlawful. If the claim is brought by us or on our behalf, we will not be obligated to indemnify the director if the director is found liable to us, unless the court determines that, despite the adjudication of liability, in view of all the circumstances of the case, the director is fairly and reasonably entitled to be indemnified. In the event that we do not assume the defense of a claim against the director, we are required to advance his or her expenses in connection with his or her defense, provided that he or she undertakes to repay all amounts advanced if it is ultimately determined that he or she is not entitled to be indemnified by us. We will require that any successor to our business assumes and agrees to perform our obligations under the indemnification provisions.

In connection with our indemnification obligations we have and intend to maintain director and officer liability insurance, if available on reasonable terms. See "Indemnification of Executive Officers" for a discussion of our indemnification arrangements with Mr. Passeri.

# Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2012 regarding compensation plans (including individual compensation arrangements) under which our equity securities are authorized for issuance.

	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (1)
Equity compensation plans approved by security holders Equity compensation plans not approved by security holders	10,437,761	\$2.59	3,044,634
Total	10,437,761	\$2.59	3,044,634

<sup>(1)</sup> Comprised of 2,765,750 shares available for grant under the 2010 Stock Incentive Plan and 278,884 shares available for sale under the 2010 Employee Stock Purchase Plan. Both plans were approved by our stockholders in June 2010.

# **Compensation Committee Interlocks and Insider Participation**

During the fiscal year ended December 31, 2012, the members of our compensation committee were Ms. Bayh, Mr. Tobin and Dr. Kaitin, none of whom was a current or former officer or employee and none of whom had any related person transaction involving the company.

During the fiscal year ended December 31, 2012, none of our executive officers served as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that had one or more of its executive officers serving as a member of our board of directors or our compensation committee.

# **Compensation Committee Report**

The compensation committee has reviewed and discussed the Compensation Discussion and Analysis, required by Item 402(b) of Regulation S-K with Curis' management. Based on this review and discussion, the compensation committee recommended to our board of directors that the Compensation Discussion and Analysis be included in this proxy statement.

Submitted by the compensation committee of our board of directors.

James R. Tobin (Chair) Kenneth I. Kaitin Robert E. Martell

# PROPOSAL 2—APPROVAL OF AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN

On April 6, 2010, our board of directors adopted, the 2010 stock incentive plan, or the 2010 Plan, which was approved by our stockholders at the June 3, 2010 annual meeting of stockholders. Up to 6,000,000 shares of our common stock (subject to adjustment in the event of stock splits and other similar events) were reserved for issuance pursuant to awards granted under the 2010 Plan. On March 28, 2013, our board of directors adopted, subject to stockholder approval, the Amended and Restated 2010 Plan, whereby an additional 3,000,000 shares of our common stock were authorized to be issued under the 2010 Plan. As a result, if approved by stockholders, up to 9,000,000 shares of our common stock (subject to adjustment in the event of stock splits and other similar events) will be available for issuance pursuant to awards granted under the Amended and Restated 2010 Plan.

Our board believes that our future success depends, in large part, upon our ability to maintain a competitive position in attracting, retaining and motivating key personnel. We believe that the addition of 3,000,000 shares of our common stock under the Amended and Restated 2010 Plan will allow us to continue to recruit leading professionals at key positions within our company as well as to retain and incentivize our current employees. We believe that these additional shares, when combined with the remaining shares available for grant under the 2010 Plan, should provide us with adequate shares at least through 2015, if not longer.

In addition to increasing the number of shares of common stock available for issuance under the 2010 Plan, the Amended and Restated 2010 Plan:

- clarifies the share counting rules for purposes of the Section 162(m) per-participant limit;
- requires the accrual of dividend equivalents (as described in the Amended and Restated 2010 Plan)
  granted with respect to restricted stock units, other stock-based or cash-based awards, and performance
  awards until the applicable award is no longer subject to any restrictions on transferability or
  forfeitability; and
- clarifies that the board may not amend or modify ay outstanding award to avoid the prohibition on repricing or change any minimum vesting provisions indicated in the 2010 Plan.

# Description of the Amended and Restated 2010 Plan

The following is a summary of the Amended and Restated 2010 Plan, a copy of which is attached as Exhibit A to this proxy statement.

Number of Shares Available for Award

Up to 9,000,000 shares of our common stock (subject to adjustment in the event of stock splits and other similar events) may be issued pursuant to awards granted under the Amended and Restated 2010 Plan.

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, or SARs, 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 our common stock will cause 1.3 shares per share under the award to be removed from the available share pool. Shares covered by awards under the Amended and

Restated 2010 Plan that are forfeited, cancelled or otherwise expire without having been exercised or settled, or that are settled by cash or other non-share consideration, become available for issuance pursuant to a new award and will be credited back to the pool at the same rates described above. Shares that are tendered or withheld to pay the exercise price of an award or to satisfy tax withholding obligations are not available for issuance pursuant to new awards. Shares are subtracted for exercises of SARs using the proportion of the total SAR that is exercised, rather than the number of shares actually issued. Shares repurchased by us on the open market using proceeds from the exercise of an award will not increase the number of shares available for future grant of awards.

### Types of Awards

The Amended and Restated 2010 Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, other stock-based awards, and cash-based awards as described below.

Incentive Stock Options and Non-statutory Stock Options. Optionees receive the right to purchase a specified number of shares of common stock at a specified option price and subject to such other terms and conditions as are specified in connection with the option grant. Options may be granted only with an exercise price that is equal to or greater than the fair market value of the common stock on the date of grant provided that if our board approves the grant of an option effective as of a future date, the exercise price may be not less than 100% of the fair market value on such future date. Under present law, incentive stock options granted to optionees holding more than 10% of the voting power of Curis may not have an exercise price that is less than 110% of the fair market on the date of grant. Options may not be granted for a term in excess of ten years (five years in the case of incentive stock options granted to optionees holding more than 10% of the voting power of Curis). The Amended and Restated 2010 Plan permits the following forms of payment of the exercise price of options:

- · cash or check;
- subject to certain conditions, delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to us sufficient funds to pay the exercise price and any required tax withholding or delivery by the participant to us of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to us cash or a check sufficient to pay the exercise price and any required tax withholding;
- subject to certain conditions, delivery of shares of common stock owned by the participant valued at their fair market value;
- to the extent provided for in the applicable nonstatutory stock option agreement or approved by the board in its sole discretion, by delivery of a notice of "net exercise" to us;
- any other lawful means; or
- any combination of these forms of payment.

An option that vests solely based on the passage of time will not vest earlier than the first anniversary of its date of grant, unless the option is granted in lieu of salary, bonus or other compensation otherwise earned by or payable to the participant. Notwithstanding the foregoing, the board, either at the time the option is granted or at any time thereafter, may allow an option to accelerate and become vested, in whole or in part, prior to the first

anniversary of its date of grant, if the participant dies or becomes disabled, the participant's employment by or service to us is terminated under specified circumstances, or in the event of a merger, consolidation, sale, reorganization, recapitalization, or change in control of the Company.

Stock Appreciation Rights. A stock appreciation right, or SAR, is an award entitling the holder, upon exercise, to receive an amount in common stock or cash or a combination thereof determined by reference to appreciation, from and after the date of grant, in the fair market value of a share of common stock over the measurement price specified in the applicable SAR agreement. The measurement price may not be less than 100% of the fair market value on the date the SAR is granted; provided that if our board approves the grant of an SAR effective as of a future date, the measurement price may be not less than 100% of the fair market value on such future date. SARs may not be granted for a term in-excess of 10 years. SARs may be granted independently or in tandem with an Option.

Restricted Stock Awards. Awards of restricted stock entitle recipients to acquire shares of common stock, subject to our right to repurchase all or part of such shares from the recipient in the event that the conditions specified in the applicable award are not satisfied prior to the end of the applicable restriction period established for such award. Any dividends declared and paid by us with respect to shares of restricted stock will be paid to the participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares.

Restricted Stock Unit Awards. Restricted stock units awards entitle the recipient to receive shares of common stock to be delivered at the time such shares vest (or on a deferred basis) pursuant to the terms and conditions established by our board. To the extent a restricted stock unit award provides the recipient with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of common stock (referred to as "dividend equivalents"), the Amended and Restated 2010 Plan provides that such dividend equivalents must be subject to the same restrictions on transfer and forfeitability as the restricted stock units with respect to which such dividend equivalents are awarded.

Other Stock-Based Awards. Under the Amended and Restated 2010 Plan, our board has the right to grant other awards based upon the common stock having such terms and conditions as our board may determine, including the grant of shares based upon certain conditions, the grant of awards that are valued in whole or in part by reference to, or otherwise based on, shares of common stock, and the grant of awards entitling recipients to receive shares of common stock to be delivered in the future. Our board may also grant performance awards or cash-based awards. Any dividends or dividend equivalents with respect to other stock-based awards, cash-based awards, or performance awards must be such to the same restrictions on transfer and forfeitability as the award with respect to which such dividend equivalents are awarded.

Performance Conditions. The compensation committee may determine, at the time of grant, that an award of restricted stock, a restricted stock unit award, or other stock-based award granted to an officer will vest solely upon the achievement of specified performance criteria designed to qualify for deduction under Section 162(m) of the Code. Performance awards can also provide for cash payments of up to \$1,000,000 per calendar year per individual. The performance criteria for each such award will be based on one or more of the following measures:

 the entry into an arrangement or agreement with a third party for the development, commercialization, marketing or distribution of products, services or technologies, or for conducting a research program to discover and develop a product, service or technology, and/or the achievement of milestones under such arrangement or agreement, including events that trigger an obligation or payment right;

- the achievement of domestic and international regulatory milestones, including the submission of
  filings required to advance products, services and technologies in clinical development and the
  achievement of approvals by regulatory authorities relating to the commercialization of products,
  services and technologies;
- the achievement of discovery, preclinical and clinical stage scientific objectives, discoveries or inventions for products, services and technologies under research and development;
- the entry into or completion of a phase of clinical development for any product, service or technology, such as the entry into or completion of phase 1, 2 and/or 3 clinical trials;
- the consummation of debt or equity financing transactions, or acquisitions of business, technologies and assets;
- · new product or service releases;
- the achievement of qualitative or quantitative performance measures set forth in operating plans approved by our board from time to time;
- specified levels of product sales, net income, earnings before or after discontinued operations, interest, taxes, depreciation and/or amortization, operating profit before or after discontinued operations and/or taxes, sales, sales growth, earnings growth, cash flow or cash position, gross margins, stock price, market share, return on sales, assets, equity or investment, improvement of financial ratings, and
- achievement of balance sheet or income statement objectives or total stockholder return.

Such goals may reflect absolute entity or business unit performance or a relative comparison to the performance peer group of entities or other external measures of the selected performance criteria and may be absolute in their terms or measured against, or in relationship to, other companies comparably, similarly or alternative situated. Such performance goals may be adjusted to exclude any one or more of:

- · extraordinary items;
- gains or losses on the dispositions of discontinued operations;
- the cumulative effects of changes in accounting principles;
- · the writedown of any asset; and
- · charges for restructuring and rationalization programs.

Such performance goals may vary by participant and may be different for different awards; may be particular to a participant or the department, branch, line of business, subsidiary or other unit in which the participant works and may cover such period as may be specified by the compensation committee; and will be set by the compensation committee within the time period prescribed by, and will otherwise comply with the requirements of, Section 162(m). The compensation committee may adjust downwards, but not upwards, the cash or number of shares payable pursuant to such award, and may not waive the achievement of the applicable performance measures except in the case of the participant's death or disability or a change in control.

We believe that disclosure of any further details concerning the performance measures for any particular year may be confidential commercial or business information, the disclosure of which would adversely affect us.

### Transferability of Awards

Except as our board may otherwise determine or provide in an award, awards may not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an incentive stock option, pursuant to a qualified domestic relations order. During the life of the participant, awards are exercisable only by the participant.

### Eligibility to Receive Awards

Our employees, officers and directors, as well as consultants and advisors to us are eligible to be granted awards under the Amended and Restated 2010 Plan. Under present law, however, incentive stock options may only be granted to our employees or those of our present or future parent or subsidiary corporations.

The maximum number of shares with respect to which awards may be granted to any participant under the Amended and Restated 2010 Plan may not exceed 1,000,000 shares per calendar year. For purposes of this limit, the combination of an option in tandem with SAR is treated as a single award and each share of common stock subject to an award (including each share of common stock subject to an award of restricted stock, a restricted stock unit award, other stock-based award or performance award) shall be treated as one share.

## Plan Benefits

We cannot currently determine the benefits or number of shares subject to stock awards that may be granted in the future to executive officers, directors and employees under the Amended and Restated 2010 Plan because awards under the Amended and Restated 2010 Plan are determined by our board of directors in its discretion.

The following table sets forth information about equity-based awards granted under the 2010 stock incentive plan as of April 1, 2013, the record date for our 2013 annual meeting of stockholders, to (i) each of our current named executive officers, (ii) all current executive officers as a group, (iii) all current non-employee directors as a group, (iv) all current non-executive officers and employees as a group, (v) each nominee for director, (vi) each associate of any director, executive officer or nominee for director, and (vii) each other current 5% holder or future 5% recipient. As of April 1, 2013, the record date for our 2013 annual meeting of stockholders, there were 1,153,778 shares of our common stock outstanding and subject to equity-based awards under the 2010 stock incentive plan and 1,317,251 shares reserved for future issuance. As noted above, we are asking our shareholders to approve the Amended and Restated 2010 Plan, whereby an additional 3,000,000 shares of our common stock will be authorized for issuance. As of the record date, the closing price of our common stock as reported on the NASDAQ Global Market was \$3.12 per share.

# PLAN BENEFITS AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN

Name and Position	Number of Shares Subject to Awards (#)
Daniel R. Passeri	800,000
Michael P. Gray Chief Financial Officer	500,000
Mark W. Noel	200,000
Maurizio Voi, M.D	575,000
Ali Fattaey, Ph.D	400,000
All Current Executive Officers as a Group (5 persons)	2,475,000
All Current Non-Employee Directors as a Group (8 persons)	1,022,188
All Current Non-Executive Officers and Employees as a Group (30 persons)	842,313
Robert E. Martell, M.D., Ph.D	100,000
Daniel R. Passeri	800,000
Marc Rubin, M.D	125,000
Each associate of any Director, Executive Officer, or Nominee for Director	
Each Other Current 5% Holder a Future 5% Recipient	

### Administration

The Amended and Restated 2010 Plan is administered by our board. Our board has the authority to adopt, amend and repeal the administrative rules, guidelines and practices relating to the Amended and Restated 2010 Plan and to interpret the provisions of the Amended and Restated 2010 Plan. Our board may construe and interpret the terms of the Amended and Restated 2010 Plan and any award agreements entered into under the Amended and Restated 2010 Plan. Pursuant to the terms of the Amended and Restated 2010 Plan, our board may, subject to certain limitations, delegate authority under the Amended and Restated 2010 Plan to one or more committees or subcommittees of our board. Discretionary awards to non-employee directors may be granted and administered only by our board or a committee, all of the members of which are independent directors as defined by Section 5605(a)(2) of the NASDAQ Marketplace Rules. Subject to certain limitations, the board may delegate to one or more officers the power to grant options and other awards that are treated as rights under Delaware law and to exercise such other powers under the Amended and Restated 2010 Plan as the board may determine.

Subject to any applicable limitations contained in the Amended and Restated 2010 Plan, our board or any committee to whom our board delegates authority, as the case may be, selects the recipients of awards and determines (i) the number of shares of common stock covered by options and the dates upon which such options become

exercisable, (ii) the exercise price of options (which may not be less than 100% of fair market value of the common stock), (iii) the duration of options (which may not exceed 10 years), and (iv) the number of shares of common stock subject to any SAR, awards of restricted stock, restricted stock unit award or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price.

Adjustments for Changes in Common Stock and Certain Other Events

Our board is required to make appropriate adjustments in connection with the Amended and Restated 2010 Plan and any outstanding awards to reflect stock splits, stock dividends, recapitalizations, spin-offs and other similar changes in capitalization. The Amended and Restated 2010 Plan also contains provisions addressing the consequences of any Reorganization Event, which is defined as:

- any merger or consolidation of us with or into another entity as a result of which all of our common stock is converted into or exchanged for the right to receive cash, securities or other property, or is cancelled;
- any transfer or disposition of all of our common stock for cash, securities or other property pursuant to a share exchange or other transaction; or
- our liquidation or dissolution.

In connection with a Reorganization Event, our board of directors or the compensation committee may take any one or more of the following actions as to all or any outstanding awards (other than restricted stock) on such terms as the board or compensation committee determines:

- provide that awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice, provide that all unexercised stock options or other unexercised awards will become exercisable in full and will terminate immediately prior to the consummation of such Reorganization Event unless exercised within a specified period following the date of such notice;
- provide that outstanding awards will become realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part prior to or upon such Reorganization Event;
- in the event of a Reorganization Event under the terms of which holders of our common stock will receive, upon consummation thereof, a cash payment for each share surrendered in the Reorganization Event, or "Acquisition Price", make or provide for a cash payment to an award holder equal to (i) the Acquisition Price times the number of shares of our common stock subject to the holder's awards (to the extent the exercise price does not exceed the Acquisition Price) minus (ii) the aggregate exercise price of all the holder's outstanding awards, in exchange for the termination of such awards;
- provide that, in connection with a liquidation or dissolution of our company, awards will convert into the right to receive liquidation proceeds (if applicable, net of the exercise price thereof); and
- any combination of the foregoing.

Upon the occurrence of a Reorganization Event other than a liquidation or dissolution, our repurchase and other rights with respect to outstanding restricted stock shall inure to the benefit of our successor and shall, unless our board of directors determines otherwise, apply to the cash, securities or other property which the common stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such restricted stock; *provided*, *however*, that our board of directors may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any restricted stock or any other agreement between us and an Amended and Restated 2010 Plan participant, either initially or by amendment. Upon the occurrence of a Reorganization Event involving a

liquidation or dissolution, except to the extent specifically provided to the contrary in the instrument evidencing any restricted stock, all restrictions and conditions on all restricted stock then outstanding shall automatically be deemed terminated or satisfied.

Unless otherwise provided for in the instrument evidencing any stock option or any other agreement between us and an Amended and Restated 2010 Plan participant, effective immediately prior to a "Change in Control Event" (as this term is defined in the Amended and Restated 2010 Plan), the vesting schedule of all options and awards of restricted stock then outstanding shall be accelerated in part so that one-half of the number of shares that would otherwise have first become vested and/or free from restrictions and conditions on any date after the date of the Change in Control Event shall immediately become exercisable. The remaining one-half of such number of shares shall continue to become vested in accordance with the original vesting schedule set forth in such option or award of restricted stock, with one-half of the number of shares that would otherwise have become vested and/or free from restrictions and conditions on each subsequent vesting date in accordance with the original schedule becoming vested on each such subsequent vesting date; provided, however, that each such option and award of restricted stock shall be immediately exercisable in full and/or free from restrictions and conditions if, on or prior to the first anniversary of the date of the consummation of the Change in Control Event, the Participant's employment with the Company or the Acquiring Corporation (as this term is defined in the Amended and Restated 2010 Plan) is terminated for Good Reason (as this term is defined in the Amended and Restated 2010 Plan) by the participant or is terminated without Cause (as this term is defined in the Amended and Restated 2010 Plan) by the Company or the Acquiring Corporation.

Our board of directors may specify in an award at the time of grant the effect of a Change in Control Event on an SAR or other stock-based award.

Except as described above, our board of directors or the compensation committee may at any time provide that any award will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

If any award expires or is terminated, surrendered, canceled or forfeited, the unused shares of our common stock covered by such award will again be available for grant under the Amended and Restated 2010 Plan, subject, in the case of incentive stock options, to any limitations under the Code.

### Substitute Awards

In connection with a merger or consolidation of an entity with us or the acquisition by us of property or stock of an entity, our board may grant awards in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute awards may be granted on such terms as our board deems appropriate in the circumstances, notwithstanding any limitations on awards contained in the Amended and Restated 2010 Plan. Substitute awards will not count against the overall share limit or any sublimits under the Amended and Restated 2010 Plan, except as may be required by the Code.

### Restrictions on Repricing

Unless our stockholders approve such action (or it is appropriate under a change in capitalization, a reorganization event, or a Change in Control Event), the Amended and Restated 2010 Plan provides that we may not:

amend any outstanding stock option or SAR granted under the Amended and Restated 2010 Plan to
provide an exercise price per share that is lower than the then-current exercise or measurement price
per share of such outstanding award;

- cancel any outstanding option or SAR (whether or not granted under the Amended and Restated 2010 Plan) and grant in substitution therefor new awards under the Amended and Restated 2010 Plan (other than as substitute awards as described above) covering the same or a different number of shares of common stock and having an exercise or measurement price per share lower than the then-current exercise or measurement price per share of the cancelled award;
- cancel for cash any options or SARs that then have exercise or measurement prices per share below the fair market value of our common stock; or
- take any other action that constitutes a "repricing" within the meaning of the rules of the NASDAQ Stock Market.

# Provisions for Foreign Participants

Our board of directors or the compensation committee may modify awards granted to participants who are foreign nationals or employed outside the United States, or establish subplans or procedures under the Amended and Restated 2010 Plan to recognize differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

#### Amendment or Termination

No Award may be made under the Amended and Restated 2010 Plan after June 3, 2020 but awards previously granted may extend beyond that date. Our board of directors may at any time amend, suspend or terminate the Amended and Restated 2010 Plan; provided that, to the extent determined by the board, no amendment requiring stockholder approval under any applicable legal, regulatory or listing requirement, including amendments with regard to the prohibition on repricing or the minimum vesting provisions, will become effective until such stockholder approval is obtained.

Subject to certain limitations, the board may amend, modify or terminate any outstanding award, including but not limited to, substituting therefor another award of the same or a different type, changing the date of exercise or realization, and converting an incentive stock option to a nonstatutory stock option.

If the stockholders do not approve the adoption of the Amended and Restated 2010 Plan, the Amended and Restated 2010 Plan will not go into effect, and we will not grant any awards under the Amended and Restated 2010 Plan. In such event, our board of directors will consider whether to adopt alternative arrangements based on its assessment of our needs.

### **Federal Income Tax Consequences**

The following is a summary of the United States federal income tax consequences that generally will arise with respect to awards granted under the Amended and Restated 2010 Plan. This summary is based on the federal tax laws in effect as of the date of this proxy statement. In addition, this summary assumes that all awards are exempt from, or comply with, the rules under Section 409A of the Code regarding nonqualified deferred compensation. Changes to these laws could alter the tax consequences described below.

### **Incentive Stock Options**

A participant will not have income upon the grant of an incentive stock option. Also, except as described below, a participant will not have income upon exercise of an incentive stock option if the participant has been employed by us or our corporate parent or 50% or more-owned corporate subsidiary at all times beginning with the option grant date and ending three months before the date the participant exercises the option. If the

participant has not been so employed during that time, then the participant will be taxed as described below under "Non-statutory Stock Options." The exercise of an incentive stock option may subject the participant to the alternative minimum tax.

A participant will have income upon the sale of the stock acquired under an incentive stock option at a profit (if sales proceeds exceed the exercise price). The type of income will depend on when the participant sells the stock. If a participant sells the stock more than two years after the option was granted and more than one year after the option was exercised, then all of the profit will be long-term capital gain. If a participant sells the stock prior to satisfying these waiting periods, then the participant will have engaged in a disqualifying disposition and a portion of the profit will be ordinary income and a portion may be capital gain. This capital gain will be long-term if the participant has held the stock for more than one year and otherwise will be short-term. If a participant sells the stock at a loss (sales proceeds are less than the exercise price), then the loss will be a capital loss. This capital loss will be long-term if the participant held the stock for more than one year and otherwise will be short-term.

### Non-statutory Stock Options

A participant will not have income upon the grant of a non-statutory stock option. A participant will have compensation income upon the exercise of a non-statutory stock option equal to the value of the stock on the day the participant exercised the option less the exercise price. Upon sale of the stock, the participant will have capital gain or loss equal to the difference between the sales proceeds and the value of the stock on the day the option was exercised. This capital gain or loss will be long-term if the participant has held the stock for more than one year and otherwise will be short-term.

# Stock Appreciation Rights

A participant will not have income upon the grant of a stock appreciation right. A participant generally will recognize compensation income upon the exercise of an SAR equal to the amount of the cash and the fair market value of any stock received. Upon the sale of the stock, the participant will have capital gain or loss equal to the difference between the sales proceeds and the value of the stock on the day the SAR was exercised. This capital gain or loss will be long-term if the participant held the stock for more than one year and otherwise will be short-term.

#### Restricted Stock Awards

A participant will not have income upon the grant of restricted stock unless an election under Section 83(b) of the Code is made within 30 days of the date of grant. If a timely 83(b) election is made, then a participant will have compensation income equal to the value of the stock less the purchase price. When the stock is sold, the participant will have capital gain or loss equal to the difference between the sales proceeds and the value of the stock on the date of grant. If the participant does not make an 83(b) election, then when the stock vests the participant will have compensation income equal to the value of the stock on the vesting date less the purchase price. When the stock is sold, the participant will have capital gain or loss equal to the sales proceeds less the value of the stock on the vesting date. Any capital gain or loss will be long-term if the participant held the stock for more than one year and otherwise will be short-term.

### Restricted Stock Units

A participant will not have income upon the grant of a restricted stock unit. A participant is not permitted to make a Section 83(b) election with respect to a restricted stock unit award. When the restricted stock unit vests,

the participant will have income on the vesting date in an amount equal to the fair market value of the stock on the vesting date less the purchase price, if any. When the stock is sold, the participant will have capital gain or loss equal to the sales proceeds less the value of the stock on the vesting date. Any capital gain or loss will be long-term if the participant held the stock for more than one year and otherwise will be short-term.

### Other Stock-Based Awards

The tax consequences associated with any other stock-based award granted under the Amended and Restated 2010 Plan will vary depending on the specific terms of such award. Among the relevant factors are whether or not the award has a readily ascertainable fair market value, whether or not the award is subject to forfeiture provisions or restrictions on transfer, the nature of the property to be received by the participant under the award and the participant's holding period and tax basis for the award or underlying common stock.

### Tax Consequences to Us

There will be no tax consequences to us except that we will be entitled to a deduction when a participant has compensation income. Any such deduction will be subject to the limitations of Section 162(m) of the Code.

#### **Board Recommendation**

OUR BOARD OF DIRECTORS BELIEVES THAT THE ADOPTION OF THE AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN IS IN THE BEST INTERESTS OF CURIS AND OUR STOCKHOLDERS AND, THEREFORE, RECOMMENDS THAT YOU VOTE "FOR" THIS PROPOSAL.

# PROPOSAL 3—APPROVAL OF AMENDMENT TO RESTATED CERTIFICATE OF INCORPORATION

On March 7, 2013, our board of directors approved, subject to stockholder approval, an amendment to our Restated Certificate of Incorporation to, among other things, (i) increase the number of authorized shares of capital stock from 130,000,000 shares to 230,000,000 shares and (ii) increase the number of authorized shares of our common stock from 125,000,000 shares to 225,000,000 shares. Our Restated Certificate of Incorporation currently authorizes 125,000,000 shares of common stock, par value \$0.01 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share, of which 80,154,098 shares of common stock and zero shares of preferred stock were outstanding as of April 1, 2013. The proposed Certificate of Amendment would not increase or otherwise affect our authorized preferred stock. Our common stock is all of a single class, with equal voting, distribution, liquidation and other rights. The additional common stock to be authorized by adoption of the amendment would have rights identical to our currently outstanding common stock.

A copy of the amendment to our Restated Certificate of Incorporation is attached as <u>Exhibit B</u> to this proxy statement. If our stockholders approve the proposal, subject to the discretion of the board, we will file the amendment to the Restated Certificate of Incorporation with the Secretary of State of the State of Delaware as soon as practicable.

### Purpose

Our board of directors believes that it is in the best interests of Curis to increase the number of authorized shares of common stock in order to give us greater flexibility in considering and planning for potential business needs. The increase in the number of authorized but unissued shares of common stock would enable the company, without the expense and delay of seeking stockholder approval, to issue shares from time to time as may be required for proper business purposes.

We anticipate that we may issue additional shares of common stock in the future in connection with one or more of the following:

- financing transactions, such as public or private offerings of common stock or convertible securities;
- partnerships, collaborations and other similar transactions;
- our equity incentive plans;
- · strategic investments; and
- other corporate purposes that have not yet been identified.

At this time, we do not have any plans, commitments, arrangements, understandings or agreements regarding the issuance of common stock following the increase of our authorized shares. However, the availability of additional shares of common stock for issuance is, in management's view, prudent and will afford us flexibility in acting upon financing transactions to strengthen our financial position and/or commercial partnership opportunities that may arise.

As of April 1, 2013, a total of 80,154,098 shares of common stock were issued and outstanding, 1,047,707 were held in treasury, and there were no shares of preferred stock issued or outstanding. As of April 1, 2013, there were an aggregate of 11,749,943 options outstanding to purchase common stock under our equity incentive

plans, and warrants to purchase 1,373,517 shares of our common stock were outstanding. Additionally, an aggregate of 1,317,251 shares of common stock are reserved for future issuance under our 2010 Stock Incentive Plan and 278,884 shares of common stock are reserved for issuance under our 2010 Employee Stock Purchase Plan. Accordingly, out of the 125,000,000 shares of common stock authorized, 95,921,400 shares are issued or reserved for issuance and 29,078,600 authorized shares of common stock remain for future issuance.

#### **Possible Effects of the Amendment**

If the Certificate of Amendment of the Restated Certificate of Incorporation is approved, the additional authorized shares would be available for issuance at the discretion of our board of directors and without further stockholder approval, except as may be required by law or the rules of the Nasdaq Global Market on which our common stock is listed. The additional shares of authorized common stock would have the same rights and privileges as the shares of common stock currently issued and outstanding. Holders of our common stock have no preemptive rights.

The issuance of additional shares of common stock may, among other things, have a dilutive effect on earnings per share and on stockholders' equity and voting rights. Furthermore, future sales of substantial amounts of our common stock, or the perception that these sales might occur, could adversely affect the prevailing market price of our common stock or limit our ability to raise additional capital. Stockholders should recognize that, as a result of this proposal, they will own a smaller percentage of shares relative to the total authorized shares of the company than they presently own.

#### **Board Recommendation**

OUR BOARD OF DIRECTORS BELIEVES THAT THE APPROVAL OF THE AMENDMENT TO THE RESTATED CERTIFICATE OF INCORPORATION IS IN THE BEST INTERESTS OF CURIS AND OUR STOCKHOLDERS AND, THEREFORE, RECOMMENDS THAT YOU VOTE "FOR" THIS PROPOSAL.

# PROPOSAL 4—RATIFICATION OF THE APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The audit committee has selected PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2013. PricewaterhouseCoopers LLP has served as our independent registered public accounting firm since April 26, 2002. Although stockholder approval of the audit committee's selection of PricewaterhouseCoopers LLP is not required by law, the board and the audit committee believe that it is advisable to give stockholders an opportunity to ratify this selection. If the stockholders do not ratify the selection of PricewaterhouseCoopers LLP, the audit committee will reconsider the matter. A representative of PricewaterhouseCoopers LLP is expected to be present at the meeting to respond to appropriate questions and to make a statement if he or she so desires.

### **Board Recommendation**

OUR BOARD OF DIRECTORS BELIEVES THAT THE RATIFICATION OF THE SELECTION OF PRICEWATERHOUSE COOPERS LLP AS CURIS' INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR THE YEAR ENDING DECEMBER 31, 2013 IS IN THE BEST INTERESTS OF CURIS AND OUR STOCKHOLDERS AND THEREFORE, RECOMMENDS THAT YOU VOTE "FOR" THIS PROPOSAL.

### **OTHER MATTERS**

The board knows of no other business that will be presented for consideration at the meeting other than that described above. However, if any other business should come before the meeting, it is the intention of the persons named in the enclosed proxy card to vote, or otherwise act, in accordance with their best judgment on such matters.

## Stockholder Proposals for 2014 Annual Meeting

Any proposal that a stockholder of Curis wishes to be considered for inclusion in our proxy statement and proxy for the 2014 annual meeting of stockholders must be submitted to our secretary at our offices, 4 Maguire Road, Lexington, MA 02421, no later than December 18, 2013.

If a stockholder of Curis wishes to present a proposal at the 2014 annual meeting, but does not wish to have the proposal considered for inclusion in our proxy statement and proxy, such stockholder must also give written notice to our secretary at the address noted above. The secretary must receive such notice not less than 60 days nor more than 90 days' prior to the 2014 annual meeting; provided that, in the event that less than 70 days' notice or prior public disclosure of the date of the 2014 annual meeting is given or made, notice by the stockholder must be received not later than the close of business on the 10th day following the date on which such notice of the date of the meeting was mailed or such public disclosure was made, whichever occurs first. The date of our 2013 annual meeting has not yet been established, but assuming it is held on May 30, 2014, in order to comply with the time periods set forth in our by-laws, appropriate notice for the 2014 annual meeting would need to be provided to our secretary no earlier than March 1, 2014, and no later than March 31, 2014. If a stockholder fails to provide timely notice of a proposal to be presented at the 2014 annual meeting, the proxies designated by the board will have discretionary authority to vote on any such proposal.

### **Solicitation of Proxies**

We will bear the costs of soliciting proxies. In addition to solicitations by mail, our directors, officers and regular employees may, without additional remuneration, solicit proxies by telephone, facsimile and personal interviews. We will also request brokerage houses, custodians, nominees and fiduciaries to forward copies of the proxy material to those persons for whom they hold shares and request instructions for voting the proxies. We will reimburse such brokerage houses and other persons for their reasonable expenses in connection with this distribution.

### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our directors, executive officers and holders of more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Based solely on our review of copies of reports filed by the reporting persons furnished to us, we believe that during the fiscal year ended December 31, 2012, the reporting persons complied with all Section 16(a) filing requirements.

### **Householding of Annual Meeting Materials**

Some banks, brokers and other nominee record holders may be participating in the practice of "householding" proxy statements and annual reports. This means that only one copy of this proxy statement or our 2012 annual report to stockholders may have been sent to multiple stockholders in your household. We will promptly deliver a separate copy of either document if you write or call us at the following address or telephone number: 4 Maguire Road, Lexington, MA 02421, Attention: Secretary, (617) 503-6500. If you want separate copies of the proxy statement and 2012 annual report to stockholders in the future, or if you are receiving multiple copies and would like to receive only one copy for your household, you should contact your bank, broker or other nominee record holder, or you may contact us at the above address or telephone number.

THE BOARD HOPES THAT STOCKHOLDERS WILL ATTEND THE MEETING. WHETHER OR NOT YOU PLAN TO ATTEND, WE URGE YOU TO VOTE YOUR SHARES OVER THE INTERNET OR BY TELEPHONE, OR COMPLETE, DATE, SIGN AND RETURN THE ENCLOSED PROXY CARD IN THE ACCOMPANYING ENVELOPE. NO POSTAGE NEED BE AFFIXED IF THE PROXY CARD IS MAILED IN THE UNITED STATES. PROMPT RESPONSE WILL GREATLY FACILITATE ARRANGEMENTS FOR THE MEETING AND YOUR COOPERATION IS APPRECIATED. STOCKHOLDERS WHO ATTEND THE MEETING MAY VOTE THEIR STOCK PERSONALLY EVEN THOUGH THEY HAVE VOTED OVER THE INTERNET, BY TELEPHONE OR SENT IN THEIR PROXY CARDS.

By Order of the Board of Directors,

/s/ Michael P. Gray

Michael P. Gray Chief Financial Officer, Secretary

Lexington, Massachusetts April 17, 2013

#### CURIS, INC.

### AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN

### 1. Purpose

The purpose of this Amended and Restated 2010 Stock Incentive Plan (the "Plan") of Curis, Inc., a Delaware corporation (the "Company"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "Company" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "Code") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "Board").

### 2. Eligibility

All of the Company's employees, officers and directors, as well as consultants and advisors to the Company (as such terms are defined and interpreted for purposes of Form S-8 under the Securities Act of 1933, as amended (the "Securities Act"), or any successor form) are eligible to be granted Awards under the Plan. Each person who is granted an Award under the Plan is deemed a "Participant." "Award" means Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Stock (as defined in Section 7), Restricted Stock Units (as defined in Section 7), Other Stock-Based Awards and Cash-Based Awards (each as defined in Section 8).

### Administration and Delegation

- (a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.
- (b) <u>Appointment of Committees</u>. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "Committee"). All references in the Plan to the "Board" shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or officers.
- (c) <u>Delegation to Officers</u>. To the extent permitted by applicable law, the Board may delegate to one or more officers of the Company the power to grant Options and other Awards that constitute rights under Delaware law (subject to any limitations under the Plan) to employees or officers of the Company and to exercise such

other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of such Awards to be granted by such officers (including the exercise price of such Awards, which may include a formula by which the exercise price will be determined) and the maximum number of shares subject to such Awards that the officers may grant; provided further, however, that no officer shall be authorized to grant such Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) or to any "officer" of the Company (as defined by Rule 16a-1 under the Exchange Act). The Board may not delegate authority under this Section 3(c) to grant Restricted Stock, unless Delaware law then permits such delegation.

(d) <u>Awards to Non-Employee Directors</u>. Discretionary Awards to non-employee directors may be granted and administered only by the Board or a Committee, all of the members of which are independent directors as defined by Section 5605(a)(2) of the NASDAQ Marketplace Rules (the "*Independent Committee*").

### 4. Stock Available for Awards

- (a) Number of Shares; Share Counting.
- (1) <u>Authorized Number of Shares</u>. Subject to adjustment under Section 10, Awards may be made under the Plan for up to [9,000,000] shares of common stock, \$0.01 par value per share, of the Company (the "Common Stock"), any or all of which Awards may be in the form of Incentive Stock Options (as defined in Section 5(b)). Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.
- (2) Fungible Share Pool. Subject to adjustment under Section 10, any Award that is not a Full-Value Award shall be counted against the share limit specified in Section 4(a)(1) as one share for each share of Common Stock subject to such Award and any Award that is a Full-Value Award shall be counted against the share limit specified in Section 4(a)(1) as [1.3] shares for each one share of Common Stock subject to such Full-Value Award. "Full-Value Award" means any Award of Restricted Stock, Restricted Stock Unit Award, Other Stock-Based Award or Performance Award with a per share price or per unit purchase price lower than 100% of Fair Market Value (as defined below) on the date of grant. To the extent a share that was subject to an Award that counted as one share is returned to the Plan pursuant to Section 4(a)(3), each applicable share reserve will be credited with one share. To the extent that a share that was subject to an Award that counts as [1.3] shares is returned to the Plan pursuant to Section 4(a)(3), each applicable share reserve will be credited with [1.3] shares.
- (3) <u>Share Counting</u>. For purposes of counting the number of shares available for the grant of Awards under the Plan:
- (A) all shares of Common Stock covered by SARs shall be counted against the number of shares available for the grant of Awards under the Plan; provided, *however*, that (i) SARs that may be settled only in cash shall not be so counted and (ii) if the Company grants an SAR in tandem with an Option for the same number of shares of Common Stock and provides that only one such Award may be exercised (a "*Tandem SAR*"), only the shares covered by the Option, and not the shares covered by the Tandem SAR, shall be so counted, and the expiration of one in connection with the other's exercise will not restore shares to the Plan;
- (B) if any Award (i) expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase

- right) or (ii) results in any Common Stock not being issued (including as a result of an SAR that was settleable either in cash or in stock actually being settled in cash), the unused Common Stock covered by such Award shall again be available for the grant of Awards; *provided*, *however*, that (1) in the case of Incentive Stock Options, the foregoing shall be subject to any limitations under the Code, (2) in the case of the exercise of an SAR, the number of shares counted against the shares available under the Plan shall be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle such SAR upon exercise and (3) the shares covered by a Tandem SAR shall not again become available for grant upon the expiration or termination of such Tandem SAR;
- (C) shares of Common Stock delivered (either by actual delivery, attestation, or net exercise) to the Company by a Participant to (i) purchase shares of Common Stock upon the exercise of an Award or (ii) satisfy tax withholding obligations (including shares retained from the Award creating the tax obligation) shall not be added back to the number of shares available for the future grant of Awards; and
- (D) shares of Common Stock repurchased by the Company on the open market using the proceeds from the exercise of an Award shall not increase the number of shares available for future grant of Awards.
- (b) Section 162(m) Per-Participant Limit. Subject to adjustment under Section 10, the maximum number of shares of Common Stock with respect to which Awards may be granted to any Participant under the Plan shall be 1,000,000 per calendar year. For purposes of the foregoing limit, (i) the combination of an Option in tandem with an SAR shall be treated as a single Award and (ii) each share of Common Stock subject to an Award (including each share of Common Stock subject to a Full-Value Award) shall be treated as one share. The per Participant limit described in this Section 4(b) shall be construed and applied consistently with Section 162(m) of the Code or any successor provision thereto, and the regulations thereunder ("Section 162(m)").
- (c) <u>Substitute Awards</u>. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Awards in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a)(1) or any sublimits contained in the Plan, except as may be required by reason of Section 422 and related provisions of the Code.

### 5. Stock Options

- (a) <u>General</u>. The Board may grant options to purchase Common Stock (each, an "*Option*") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable.
- (b) <u>Incentive Stock Options</u>. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "*Incentive Stock Option*") shall only be granted to employees of Curis, Inc., any of Curis, Inc.'s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. An Option that is not intended to be an Incentive Stock Option shall be designated a "*Nonstatutory Stock Option*."

The Company shall have no liability to a Participant, or any other party, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or if the Company converts an Incentive Stock Option to a Nonstatutory Stock Option.

- (c) Exercise Price. The Board shall establish the exercise price of each Option and specify the exercise price in the applicable Option agreement. The exercise price shall be not less than 100% of the Fair Market Value (as defined below) per share of Common Stock on the date the Option is granted; *provided* that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Fair Market Value on such future date. "Fair Market Value" of a share of Common Stock for purposes of the Plan will be determined as follows:
- (1) if the Common Stock trades on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or
- (2) if the Common Stock does not trade on any such exchange, the average of the closing bid and asked prices as reported by an authorized OTCBB market data vendor as listed on the OTCBB website (otcbb.com) on the date of grant; or
- (3) if the Common Stock is not publicly traded, the Board will determine the Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Code Section 409A, except as the Board may expressly determine otherwise.

For any date that is not a trading day, the Fair Market Value of a share of Common Stock for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of "closing sale price" or "bid and asked prices" if appropriate because of exchange or market procedures or can, in its sole discretion, use weighted averages either on a daily basis or such longer period as complies with Code Section 409A.

The Board has sole discretion to determine the Fair Market Value for purposes of the Plan, and all Awards are conditioned on the participants' agreement that the Administrator's determination is conclusive and binding even though others might make a different determination.

- (d) <u>Duration of Options</u>. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement; *provided*, *however*, that no Option will be granted with a term in excess of 10 years.
- (e) Exercise of Options. Options may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with payment in full (in the manner specified in Section 5(f)) of the exercise price for the number of shares for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise.
- (f) <u>Payment Upon Exercise</u>. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:
  - (1) in cash or by check, payable to the order of the Company;

- (2) except as may otherwise be provided in the applicable Option agreement or approved by the Board, in its sole discretion, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;
- (3) to the extent provided for in the applicable Option agreement or approved by the Board, in its sole discretion, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their Fair Market Value, provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board in its discretion and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;
- (4) to the extent provided for in the applicable Nonstatutory Stock Option agreement or approved by the Board in its sole discretion, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the Fair Market Value on the date of exercise;
- (5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board, in its sole discretion, by payment of such other lawful consideration as the Board may determine; or
  - (6) by any combination of the above permitted forms of payment.
- (g) Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 10): (1) amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option, (2) cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(c)) covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled option, (3) cancel in exchange for a cash payment any outstanding Option with an exercise price per share below the then-current Fair Market Value, other than pursuant to Section 10, or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the NASDAQ Stock Market ("NASDAQ").
- (h) Minimum Vesting. Other than with respect to Options granted to non-employee directors, no Option that vests solely based on the passage of time shall vest earlier than the first anniversary of its date of grant, unless the Option is granted in lieu of salary, bonus or other compensation otherwise earned by or payable to the Participant. Notwithstanding the foregoing, the Board, either at the time the Option is granted or at any time thereafter, may allow an Option to accelerate and become vested, in whole or in part, prior to the first anniversary of its date of grant, in the event of the death or disability of the Participant; the termination of the Participant's employment by or service to the Company under specified circumstances; or a merger, consolidation, sale, reorganization, recapitalization, or change in control of the Company.

### 6. Stock Appreciation Rights

- (a) General. The Board may grant Awards consisting of stock appreciation rights ("SARs") entitling the holder, upon exercise, to receive an amount of Common Stock or cash or a combination thereof (such form to be determined by the Board) determined by reference to appreciation, from and after the date of grant, in the Fair Market Value of a share of Common Stock over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date.
- (b) Measurement Price. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Fair Market Value on the date the SAR is granted; provided that if the Board approves the grant of an SAR effective as of a future date, the measurement price shall be not less than 100% of the Fair Market Value on such future date.
- (c) <u>Duration of SARs</u>. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; *provided*, *however*, that no SAR will be granted with a term in excess of 10 years.
- (d) Exercise of SARs. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.
- (e) <u>Limitation on Repricing</u>. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 10): (1) amend any outstanding SAR granted under the Plan to provide a measurement price per share that is lower than the then-current measurement price per share of such outstanding SAR, (2) cancel any outstanding SAR (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(c)) covering the same or a different number of shares of Common Stock and having an exercise or measurement price per share lower than the then-current measurement price per share of the cancelled SAR, (3) cancel in exchange for a cash payment any outstanding SAR with a measurement price per share below the then-current Fair Market Value, other than pursuant to Section 10, or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the NASDAQ.

### 7. Restricted Stock; Restricted Stock Units

- (a) General. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("Restricted Stock"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive shares of Common Stock or cash to be delivered at the time such Award vests ("Restricted Stock Units") (Restricted Stock and Restricted Stock Units are each referred to herein as a "Restricted Stock Award").
- (b) <u>Terms and Conditions for All Restricted Stock Awards</u>. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.
  - (c) Additional Provisions Relating to Restricted Stock.

- (1) <u>Dividends</u>. Unless otherwise provided in the applicable Award agreement, any dividends (whether paid in cash, stock or property) declared and paid by the Company with respect to shares of Restricted Stock ("Accrued Dividends") shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Accrued Dividends will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying shares of Restricted Stock.
- (2) Stock Certificates. The Company may require that any stock certificates issued in respect of shares of Restricted Stock, as well as dividends or distributions paid on such Restricted Stock, shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. "Designated Beneficiary" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, the Participant's estate.

### (d) Additional Provisions Relating to Restricted Stock Units.

- (1) Settlement. Upon the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each Restricted Stock Unit, the Participant shall be entitled to receive from the Company one share of Common Stock or (if so provided in the applicable Award agreement) an amount of cash equal to the Fair Market Value of one share of Common Stock. The Board may, in its discretion, provide that settlement of Restricted Stock Units shall be deferred, on a mandatory basis or at the election of the Participant in a manner that complies with Section 409A of the Code.
  - (2) Voting Rights. A Participant shall have no voting rights with respect to any Restricted Stock Units.
- (3) <u>Dividend Equivalents</u>. The Award agreement for Restricted Stock Units may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of Common Stock ("*Dividend Equivalents*"). Dividend Equivalents may be settled in cash and/or shares of Common Stock. Any Dividend Equivalents must be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which such Dividend Equivalents are awarded.

### 8. Other Stock-Based Awards

- (a) <u>General</u>. Other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property, may be granted hereunder to Participants ("Other Stock-Based Awards"). Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine. The Company may also grant Performance Awards or other Awards denominated in cash rather than shares of Common Stock ("Cash-Based Awards").
- (b) <u>Terms and Conditions</u>. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award or Cash-Based Award, including any purchase price applicable

thereto. Any Dividend Equivalents with respect to Other Stock-Based Awards or Cash-Based Awards must be subject to the same restrictions on transfer and forfeitability as the Awards with respect to which such Dividend Equivalents are awarded.

### Performance Awards.

- (a) <u>Grants</u>. Restricted Stock Awards and Other Stock-Based Awards under the Plan may be made subject to the achievement of performance goals pursuant to this Section 9(a) ("*Performance Awards*"). Subject to Section 9(d), no Performance Awards shall vest prior to the first anniversary of the date of grant. Performance Awards can also provide for cash payments of up to \$1.0 million per calendar year per individual.
- (b) Committee. Grants of Performance Awards to any Covered Employee (as defined below) intended to qualify as "performance-based compensation" under Section 162(m) ("Performance-Based Compensation") shall be made only by a Committee (or a subcommittee of a Committee) comprised solely of two or more directors eligible to serve on a committee making Awards qualifying as "performance-based compensation" under Section 162(m). In the case of such Awards granted to Covered Employees, references to the Board or to a Committee shall be treated as referring to such Committee (or subcommittee). "Covered Employee" shall mean any person who is, or whom the Committee, in its discretion, determines may be, a "covered employee" under Section 162(m)(3) of the Code.
- (c) Performance Measures. For any Award that is intended to qualify as Performance-Based Compensation, the Committee shall specify that the degree of granting, vesting and/or payout shall be subject to the achievement of one or more objective performance measures established by the Committee, which shall be based on the relative or absolute attainment of any combination of the following: (i) the entry into an arrangement or agreement with a third party for the development, commercialization, marketing or distribution of products, services or technologies, or for conducting a research program to discover and develop a product, service or technology, and/or the achievement of milestones under such arrangement or agreement, including events that trigger an obligation or payment right; (ii) achievement of domestic and international regulatory milestones, including the submission of filings required to advance products, services and technologies in clinical development and the achievement of approvals by regulatory authorities relating to the commercialization of products, services and technologies; (iii) the achievement of discovery, preclinical and clinical stage scientific objectives, discoveries or inventions for products, services and technologies under research and development; (iv) the entry into or completion of a phase of clinical development for any product, service or technology, such as the entry into or completion of phase 1, 2 and/or 3 clinical trials; (v) the consummation of debt or equity financing transactions, or acquisitions of business, technologies and assets; (vi) new product or service releases; (vii) the achievement of qualitative or quantitative performance measures set forth in operating plans approved by the Board from time to time; and/or (viii) specified levels of product sales, net income, earnings before or after discontinued operations, interest, taxes, depreciation and/or amortization, operating profit before or after discontinued operations and/or taxes, sales, sales growth, earnings growth, cash flow or cash position, gross margins, stock price, market share, return on sales, assets, equity or investment, improvement of financial ratings and (ix) achievement of balance sheet or income statement objectives or total stockholder return. Such goals may reflect absolute entity or business unit performance or a relative comparison to the performance of a peer group of entities or other external measure of the selected performance criteria and may be absolute in their terms or measured against or in relationship to other companies comparably, similarly or otherwise situated. The Committee may specify that such performance measures shall be adjusted to exclude any one or more of (i) extraordinary items, (ii) gains or losses on the dispositions of discontinued operations, (iii) the cumulative

effects of changes in accounting principles, (iv) the writedown of any asset, and (v) charges for restructuring and rationalization programs. Such performance measures: (i) may vary by Participant and may be different for different Awards; (ii) may be particular to a Participant or the department, branch, line of business, subsidiary or other unit in which the Participant works and may cover such period as may be specified by the Committee; and (iii) shall be set by the Committee within the time period prescribed by, and shall otherwise comply with the requirements of, Section 162(m). Awards that are not intended to qualify as Performance-Based Compensation may be based on these or such other performance measures as the Board may determine.

- (d) Adjustments. Notwithstanding any provision of the Plan, with respect to any Performance Award that is intended to qualify as Performance-Based Compensation, the Committee may adjust downwards, but not upwards, the cash or number of shares payable pursuant to such Award, and the Committee may not waive the achievement of the applicable performance measures except in the case of the death or disability of the Participant or a change in control of the Company.
- (e) Other. The Committee shall have the power to impose such other restrictions on Performance Awards as it may deem necessary or appropriate to ensure that such Awards satisfy all requirements for Performance-Based Compensation. Any Dividends and/ or Dividend Equivalents with respect to Performance Awards must be subject to the same restrictions on transfer and forfeitability as the Awards with respect to which such Dividends and/or Dividend Equivalents are awarded.

### 10. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the share counting rules and sublimits set forth in Sections 4(a) and 4(b), (iii) the number and class of securities and exercise price per share of each outstanding Option, (iv) the share and per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding Restricted Stock Award and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding Other Stock-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

### (b) Reorganization Events.

(1) <u>Definition</u>. A "*Reorganization Event*" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

## (2) Consequences of a Reorganization Event on Awards Other than Restricted Stock.

(A) In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Stock on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable, or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of shares of Common Stock subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 10(b)(2), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

(B) Notwithstanding the terms of Section 10(b)(2)(A), in the case of outstanding Restricted Stock Units that are subject to Section 409A of the Code: (i) if the applicable Restricted Stock Unit agreement provides that the Restricted Stock Units shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 10(b)(2)(A)(i) and the Restricted Stock Units shall instead be settled in accordance with the terms of the applicable Restricted Stock Unit agreement; and (ii) the Board may only undertake the actions set forth in clauses (iii), (iv) or (v) of Section 10(b)(2)(A) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A of the Code; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A of the Code, and the acquiring or succeeding corporation does not assume or substitute the Restricted Stock Units pursuant to clause (i) of Section 10(b)(2)(A), then the unvested Restricted Stock Units shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

(C) For purposes of Section 10(b)(2)(A)(i), an Award (other than Restricted Stock) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each share of Common Stock subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were

offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determined to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

(3) Consequences of a Reorganization Event on Restricted Stock. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Stock shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Stock; *provided*, *however*, that the Board may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, either initially or by amendment. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock then outstanding shall automatically be deemed terminated or satisfied.

### (c) Change in Control Events.

### (1) Definitions.

### (A) A "Change in Control Event" shall mean:

(i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) 50% or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (A), the following acquisitions shall not constitute a Change in Control Event: (1) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company)], (2) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (3) any acquisition by any corporation pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (iii) of this definition; or

(ii) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "Continuing Director" means at any date a member of

the Board (x) who was a member of the Board on the date of the initial adoption of the Plan by the Board or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; *provided, however*, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or

(iii) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 50% or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

(iv) the liquidation or dissolution of the Company.

(B) "Good Reason" shall mean any significant diminution in the Participant's duties, authority, or responsibilities from and after such Reorganization Event or Change in Control Event, as the case may be, or any material reduction in the base compensation payable to the Participant from and after such Reorganization Event or Change in Control Event, as the case may be, or the relocation of the place of business at which the Participant is principally located to a location that is greater than 50 miles from its location immediately prior to such Reorganization Event or Change in Control Event. Notwithstanding the occurrence of any such event or circumstance, such occurrence shall not be deemed to constitute Good Reason unless (x) the Participant gives the Company the notice of termination no more than 90 days after the initial existence of such event or circumstance, (y) such event or circumstance has not been fully corrected and the Participant has not been reasonably compensated for any losses or damages resulting therefrom within 30 days of the Company's receipt of such notice and (z) the Participant's termination of employment occurs within six months following the Company's receipt of such notice.

(C) "Cause" shall mean any (i) willful failure by the Participant, which failure is not cured within 30 days of written notice to the Participant from the Company, to perform his or her material responsibilities to the Company or (ii) willful misconduct by the Participant which affects the business reputation of the Company.

- (2) Effect on Options. Notwithstanding the provisions of Section 10(b), effective immediately prior to a Change in Control Event, except to the extent specifically provided to the contrary in the instrument evidencing any Option or any other agreement between a Participant and the Company, the vesting schedule of such Option shall be accelerated in part so that one-half of the number of shares that would otherwise have first become vested on any date after the date of the Change in Control Event shall immediately become exercisable. The remaining one-half of such number of shares shall continue to become vested in accordance with the original vesting schedule set forth in such Option, with one-half of the number of shares that would otherwise have become vested on each subsequent vesting date in accordance with the original schedule becoming vested on each subsequent vesting date; provided, however, that each such Option shall be immediately exercisable in full if, on or prior to the first anniversary of the date of the consummation of the Change in Control Event, the Participant's employment with the Company or the Acquiring Corporation.
- (3) Effect on Restricted Stock Awards. Notwithstanding the provisions of Section 10(b), effective immediately prior to a Change in Control Event, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock Award or any other agreement between a Participant and the Company, the vesting schedule of all Restricted Stock Awards shall be accelerated in part so that one-half of the number of shares that would otherwise have first become free from conditions or restrictions on any date after the date of the Change in Control Event shall immediately become free from conditions or restrictions. Subject to the following sentence, the remaining one-half of such number of shares shall continue to become free from conditions or restrictions in accordance with the original schedule set forth in such Restricted Stock Award, with one-half of the number of shares that would otherwise have become free from conditions or restrictions on each subsequent vesting date in accordance with the original schedule becoming free from conditions or restrictions on each subsequent vesting date. In addition, each such Restricted Stock Award shall immediately become free from all conditions or restrictions if, on or prior to the first anniversary of the date of the consummation of the Change in Control Event, the Participant's employment with the Company or the Acquiring Corporation is terminated for Good Reason by the Participant or is terminated without Cause by the Company or the Acquiring Corporation.
- (4) Effect on SARs and Other Stock-Based Awards. The Board may specify in an Award at the time of the grant the effect of a Change in Control Event on any SAR and Other Stock-Based Award.
- (5) Section 409A. The definition of Change in Control Event for purposes of the Plan is intended to conform to the description of "Change in Control Events" in Treasury Regulation section 1.409A-3(i)(5), or in subsequent IRS guidance describing what constitutes a change in control event for purposes of Section 409A of the Code when the Award is subject to Section 409A. Accordingly, no Change in Control Event will be deemed to provide for acceleration of payment with respect to a transaction or event described in this Section 10(c) unless the transaction or event would constitute a "Change in Control Event" as described in Treasury Regulation section 1.409A-3(i)(5), or in subsequent IRS guidance under Section 409A of the Code. If the transaction or event described in this Section 10(c) would not constitute a "Change in Control Event" as described in Treasury Regulation section 1.409A-3(i)(5), or in subsequent IRS guidance under Section 409A of the Code, then, in connection with such transaction or event, Awards that are subject to Section 409A will be treated as provided under Section 10(b).

### 11. General Provisions Applicable to Awards

- (a) Transferability of Awards. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant; provided, however, that the Board may permit or provide in an Award for the gratuitous (i.e., not for value) transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act for the registration of the sale of the Common Stock subject to such Award to such proposed transferee; provided further, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 11(a) shall be deemed to restrict a transfer to the Company.
- (b) <u>Documentation</u>. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.
- (c) <u>Board Discretion</u>. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.
- (d) <u>Termination of Status</u>. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.
- (e) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may decide to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Board in its sole discretion, a Participant may satisfy such tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value; provided, however, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income). Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

- (f) Amendment of Award. Except as otherwise provided in Sections 5(g) and 6(e) with respect to repricings or Sections 5(h) and 9(a) with respect to the vesting of Awards, the Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 10.
- (g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.
- (h) Acceleration. Except as otherwise provided in Sections 5(h) or 9(a), the Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

### 12. Miscellaneous

- (a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.
- (b) No Rights As Stockholder. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares.
- (c) <u>Effective Date and Term of Plan</u>. The Plan shall become effective on the date the Plan is approved by the Company's stockholders (the "*Effective Date*"). No Awards shall be granted under the Plan after the expiration of 10 years from the Effective Date, but Awards previously granted may extend beyond that date.
- (d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time provided that (i) to the extent required by Section 162(m), no Award granted to a Participant that is intended to comply with Section 162(m) after the date of such amendment shall become exercisable, realizable or vested, as applicable to such Award, unless and until the Company's stockholders approve such amendment in the manner required by Section 162(m); (ii) no amendment that would require stockholder approval under the rules of the NASDAQ may be made effective unless and until the Company's stockholders approve such amendment; and (iii) if the NASDAQ amends its corporate governance rules so that such rules no longer require stockholder approval of "material amendments" to equity compensation plans,

then, from and after the effective date of such amendment to the NASDAQ rules, no amendment to the Plan (A) materially increasing the number of shares authorized under the Plan (other than pursuant to Section 4(c) or 10), (B) expanding the types of Awards that may be granted under the Plan, or (C) materially expanding the class of participants eligible to participate in the Plan shall be effective unless and until the Company's stockholders approve such amendment. In addition, if at any time the approval of the Company's stockholders is required as to any other modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Stock Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 12(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan. No Award shall be made that is conditioned upon stockholder approval of any amendment to the Plan unless the Award provides that (i) it will terminate or be forfeited if stockholder approval of such amendment is not obtained within no more than 12 months from the date of grant and (2) it may not be exercised or settled (or otherwise result in the issuance of Common Stock) prior to such stockholder approval.

- (e) Authorization of Sub-Plans (including for Grants to non-U.S. Employees). The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.
- (f) Compliance with Section 409A of the Code. Except as provided in individual Award agreements initially or by amendment, if and to the extent any portion of any payment, compensation or other benefit provided to a Participant in connection with his or her employment termination is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code and the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, as determined by the Company in accordance with its procedures, by which determination the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A of the Code) (the "New Payment Date"), except as Section 409A of the Code may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A of the Code but do not to satisfy the conditions of that section.

(g) <u>Limitations on Liability</u>. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse,

beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

# CERTIFICATE OF AMENDMENT OF RESTATED CERTIFICATE OF INCORPORATION OF CURIS, INC.

Curis, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify:

FIRST: That the Board of Directors of the Corporation has duly adopted resolutions authorizing and approving an amendment to the Restated Certificate of Incorporation of the Corporation to (i) increase the number of authorized shares of capital stock of the Corporation and (ii) increase the number of authorized shares of Common Stock of the Corporation.

SECOND: That the amendment to the Restated Certificate of Incorporation of the Corporation set forth in this Certificate of Amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of Delaware by the Board of Directors and holders of a majority of the outstanding stock of the Corporation entitled to vote thereon.

THIRD: That upon the effectiveness of this Certificate of Amendment, the first paragraph of Article FOURTH of the Restated Certificate of Incorporation is hereby amended and restated as follows:

"FOURTH: The Corporation is authorized to issue two classes of capital stock, one of which is designated as common stock, \$.01 par value per share ("Common Stock"), and the other of which is designated as preferred stock, \$.01 par value per share ("Preferred Stock"). The total number of shares of both classes of capital stock that the Corporation shall have authority to issue is [\_\_\_\_\_] shares, consisting of [\_\_\_\_\_] shares of Common Stock and 5,000,000 shares of Preferred Stock. The Preferred Stock may be issued from time to time in one or more series as set forth in Section (b) of this Article FOURTH. The following is a statement of the designations and the powers, preferences and rights of, and the qualifications, limitations or restrictions applicable to, each class of capital stock of the Corporation."

IN WITNESS WHEREOF, this Certificate of Amendmexecuted by a duly authorized officer of the Corporation on	-
	By: Dan Passeri Title: Chief Executive Officer

### CUDC-101: Preclinical EGFR/HER2 and HDAC Inhibitor

CUDC-101 is a drug candidate that is designed to target epidermal growth factor receptor, or EGFR, human epidermal growth factor receptor 2, or HER2, and HDAC. In 2012, we initiated a Phase I clinical trial of an oral formulation of CUDC-101. We subsequently terminated this study due to insufficient drug exposure observed in the first cohort of patients. We are currently assessing alternative formulations that may provide improved drug exposure for patients and therefore be more amenable to the oral route of administration. We believe that this molecule could have potential activity in several cancers if we are successful in these efforts, and expect to determine in 2013 whether we can progress an oral formulation toward clinical testing.

### DEBIO 0932: Phase I/II HSP90 Inhibitor

Debio 0932 is a synthetic, non-geldanamycin, orally available small molecule heat shock protein 90, or Hsp90, inhibitor, which we licensed to Debiopharm in August 2009. Debiopharm made significant progress with this molecule in 2012, reporting clinical results at the American Society of Clinical Oncology's annual meeting in 2012 which included single agent partial responses in patients with KRAS-mutated non-small cell lung cancer and breast cancer and what appears to be a favorable safety profile.

Debiopharm continued to progress clinical development in 2012, initiating a Phase Ib study and a Phase I/II study of Debio 0932 in advanced non-small cell lung cancer patients. Debiopharm also plans to expand its development efforts to test the molecule in patients with advanced renal cell carcinoma in 2013. We are entitled to receive milestone payments upon Debiopharm's treatment of the fifth patient in a Phase II clinical trial and we currently anticipate that Phase II testing could initiate in 2014 for both the non-small cell lung cancer and renal cell carcinoma studies.

\*\* \*\* \*\*

We are dedicated and committed to furthering the development and evolution of Curis by continuing to effectively execute our stated strategic plans with the objective of creating and maintaining significant value growth for our stockholders. We have achieved a great deal of progress during the past year and look forward to continued progress and realization of potential value creation in the years ahead.

As always, we thank our stockholders for their continued support, our Board of Directors and our advisory boards for their expert guidance, and Curis employees for their continued loyalty, hard work and dedication.

Sincerely,

Daniel R. Passeri Chief Executive Officer Curis, Inc. Sincerely,

Ali Fattaey, Ph.D.
President and Chief Operating Officer
Curis, Inc.

FORM-IOK

Curis 2012

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

# **FORM 10-K**

(Mark one)  ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  ACT OF 1934						
For the fiscal year ended December 31, 2012						
OR						
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934						
Commission File Number 000-30347						
CURIS, INC.  (Exact Name of Registrant as Specified in Its Charter)  DELAWARE  (Exact Name of Registrant as Specified in Its Charter)  Od-3505116  Section						
(C) A A A A A A A A A A A A A A A A A A A						
(State or other jurisdiction of incorporation or organization)  (I.R.S. Employer, Identification No.) 03 2013						
4 Maguire Road  Lexington, Massachusetts 02421  (Address of principal executive offices) (Zip Code)  617-503-6500  (Registrant's telephone number, including area code)  Washington DC  405						
Complete and appropriate Continue 12(h) of the Acts						
Securities registered pursuant to Section 12(b) of the Act:  Title of Each Class  Name of Each Exchange on Which Registered  The NASDAO Steel Modest						
Common Stock, \$0.01 par value per share  The NASDAQ Stock Market  Securities registered pursuant to Section 12(g) of the Act:						
None						
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes $\square$ No $\boxtimes$						
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 $\square$ No $\boxtimes$						
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. $\boxtimes$ Yes $\square$ 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). $\boxtimes$ Yes $\square$ 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 ⊠						
Non-accelerated filer						
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes \(\simega\) No \(\Simega\)						
The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) based on the last reported sale price of the common stock on June 30, 2012 was approximately \$279,356,000.						
As of March 6, 2013, there were 80,122,031 shares of the registrant's common stock outstanding.  DOCUMENTS INCORPORATED BY REFERENCE						
Specified portions of the registrant's proxy statement for the annual meeting of stockholders scheduled to be held on May 30, 2013, which are to be filed with the Commission not later than 120 days after the close of the Registrant's fiscal year ended December 31, 2012 pursuant to Regulation 14A, have been incorporated by reference in Item 5 of Part II and Items 10-14 of Part III of this Annual Report on Form 10-K.						

# CURIS, INC.

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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 IA-Risk Factors" and elsewhere in this annual report and that are otherwise described from time to time in our Securities and Exchange Commission reports filed after this report.

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

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

### ITEM 1. BUSINESS

### Overview

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

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

• In November 2012, we licensed from Genentech the exclusive, worldwide rights for the development and commercialization a small molecule drug candidate, CUDC-427, which is designed to promote cancer cell death by antagonizing inhibitors of apoptosis, or IAP, proteins. Under the terms of the license agreement, we have the sole right and responsibility for all research, development, manufacturing and commercialization activities related to CUDC-427 and we currently expect to initiate clinical studies of this drug candidate during 2013.

- We recently initiated clinical development of CUDC-907, an orally bioavailable small molecule drug candidate that is designed to inhibit phosphatidylinositol-3-kinase, or PI3K, and histone deacetylase, or HDAC, enzymes. In November 2011, we entered into an agreement with The Leukemia & Lymphoma Society, or LLS, under which LLS will make milestone payments of up to \$4,000,000 to support the Company's ongoing development of CUDC-907 in patients with relapsed or refractory lymphomas and multiple myeloma. In January 2013, we treated the first patient in a phase I clinical study of CUDC-907 and as of March 6, 2013, the first cohort of 3 patients has been enrolled in this study.
- We are a party to a license agreement with Debiopharm S.A., or Debiopharm, pursuant to which Debiopharm is developing heat shock protein 90, or HSP90, inhibitor Debio 0932. Debio 0932 recently completed phase Ib testing in patients with advanced solid tumors and Debiopharm is also currently testing Debio 0932 in a phase I/II clinical trial in patients with advanced non-small cell lung cancer, or NSCLC. Debiopharm plans to initiate a phase I study of Debio 0932 in patients with renal cell carcinoma in the second half of 2013.
- We are developing CUDC-101, a first-in-class small molecule drug candidate designed to simultaneously target the epidermal growth factor receptor, or EGFR, human epidermal growth factor receptor 2, or HER2, and HDAC, each of which is a validated cancer target and important for cancer formation and maintenance. An intravenous formulation of CUDC-101 is currently being tested in a phase I clinical trial in patients with locally advanced squamous cell carcinoma of the head and neck, or SCCHN in combination with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation.

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

### **Product Development Programs**

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

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

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

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

### Erivedge® (Hedgehog Pathway Inhibitor)

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

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

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

Advanced BCC. In January 2012, Erivedge was approved by the U.S. FDA as the first and only FDA-approved medicine for adults with advanced forms of BCC. We earned a \$10,000,000 milestone payment from Genentech as a result of the FDA's approval of Erivedge in this indication. Pursuant to the terms of our collaboration agreement, we are entitled to receive royalties on net sales of Erivedge that range from 5% to high single digits, and which escalate within this range with increasing product sales. The royalty rate applicable to Erivedge may be decreased to a low-to-mid single digit royalty in certain specified circumstances, including when a competing product that binds to the same molecular target as Erivedge is approved by the applicable regulatory authority and is being sold in such country by a third party for use in the same indication as Erivedge.

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

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

payments from Genentech will first be applied to pay (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis' royalty obligations to university licensors, as described below, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by Curis enforcing its right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject to caps of \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$3,000,000 per quarter in 2015, will be applied first, to pay interest and second, principal on the loan. Curis Royalty will be entitled to receive and distribute to Curis remaining royalty and royalty-related amounts in excess of the foregoing caps, if any. In addition, if Erivedge royalties are insufficient to pay the accrued interest on the outstanding loan, the unpaid interest outstanding will be added to the principal on a quarterly basis. As a result, we will continue to record royalty revenue from Genentech but expect the majority, if not all, of such revenues, subject to the above caps, will be used to pay down the loan received from BioPharma-II.

We are also obligated to make payments to university licensors on royalties that we earn in all territories other than Australia in an amount that is equal to 5% of the royalty payments that we receive from Genentech for a period of 10 years from the first commercial sale of Erivedge, which occurred in February 2012. For royalties that we earn from Roche's potential future sales of Erivedge in Australia, we will be obligated to make payments to university licensors in an amount that is equal to 2% of Roche's direct net sales in Australia until expiration of the patent in April 2019, after which the amount will decrease to 5% of the royalty payments that we receive from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022. From the inception of our Genentech collaboration through December 31, 2012, we have incurred expenses in an aggregate amount of approximately \$2,926,000 pursuant to licensing agreements with universities related to payments that we have received from Genentech. In addition, we were obligated to issue 200,000 shares of our common stock to two university licensors upon FDA approval of Erivedge that represented \$964,000 in expense during 2012.

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

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

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

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

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

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

Genentech Hedgehog Pathway Inhibitor Collaboration Agreement. Under the terms of our June 2003 collaborative research, development and license agreement with Genentech, we granted Genentech an exclusive, global, royalty-bearing license, with the right to sublicense, to make, use, sell and import small molecule and antibody Hedgehog pathway inhibitors for human therapeutic applications, including cancer therapy. Genentech subsequently granted a sublicense to Roche for non-U.S. rights to Erivedge. Roche received this sublicense pursuant to an agreement between Genentech and Roche under which Genentech granted Roche an option to obtain a license to commercialize certain Genentech products in non-U.S. markets. In February 2010, Chugai Pharmaceutical Co., Ltd., or Chugai, exercised its right of first refusal for the development and commercialization of Erivedge in Japan pursuant to an existing agreement between Roche and Chugai.

Genentech and Roche have primary responsibility for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing. We are eligible to receive up to \$115,000,000 in contingent cash payments for the development of Erivedge or another small molecule, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives, of which we have received \$46,000,000 to date. We are also eligible to receive royalties on sales of any Hedgehog pathway inhibitor products that are successfully commercialized by Genentech and Roche, Future royalty payments related to Erivedge will service the outstanding debt and accrued interest to BioPharma-II, up to the quarterly caps for 2013, 2014 and 2015, and until the debt is fully repaid thereafter.

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

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

### Our Targeted Drug Candidates

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

CUDC-427. In November 2012, we licensed from Genentech the exclusive, worldwide rights for the development and commercialization of CUDC-427, a small molecule that is designed to promote cancer cell death by antagonizing IAP proteins. IAP proteins are a family of functionally and structurally related proteins that promote cancer cell survival by inhibiting programmed cell death, also known as apoptosis, which is a normal process inherent in every cell. Using IAP proteins and other anti-apoptotic factors, cancer cells evade apoptosis in response to a variety of signals, including those provided by anti-cancer agents such as chemotherapy, or naturally occurring inflammatory and immune signals transmitted through members of tumor necrosis factor, or TNF, family of factors. Evasion from apoptosis is a fundamental mechanism whereby human cancers develop resistance to standard anti-cancer treatments. IAP inhibitors such as CUDC-427 are designed to counteract the effects of IAP proteins, thus shifting the balance away from cancer cell survival and allowing apoptosis to proceed.

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

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

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

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

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

In November 2011, we entered into an agreement under which The Leukemia & Lymphoma Society, or LLS, will provide up to \$4,000,000 in milestone payments to support our ongoing development of CUDC-907. In January 2013, we treated the first patient in a phase I clinical study of CUDC-907 in patients with advanced lymphoma and multiple myeloma. The phase I clinical trial is designed as a standard dose escalation study in which CUDC-907 will be orally administered to patients with relapsed or refractory lymphoma or multiple myeloma. The primary objectives of the trial are to determine the maximum tolerated dose, or MTD, and recommended phase II dose for CUDC-907 administration. The secondary objectives of this study are to assess safety and tolerability, to assess pharmacokinetics, to evaluate biomarker activity and to assess preliminary anticancer activity of CUDC-907 in this patient population. In the absence of dose limiting toxicity, each patient will receive CUDC-907 orally once daily for a minimum of 21 days (1 cycle), and may continue to receive additional cycles of treatment until disease progression or other treatment discontinuation criteria are met. Through March 6, 2013, we have earned \$1,100,000 in milestone payments under the terms of the agreement with LLS. We will be obligated to make future contingent payments, including potential royalty payments under our agreement with LLS upon our successful entry into a partnering agreement for CUDC-907 or upon the achievement of regulatory and commercial objectives, with such payments being limited to a maximum of 2.5 times the actual milestone payments that we receive from LLS under this agreement. If clinical development of CUDC-907 does not continue to meet its clinical safety endpoints in future clinical trials in the defined field or fails to obtain necessary regulatory approvals, all funding provided by LLS will be considered a non-repayable grant.

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

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

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

To date, we have completed two clinical trials with an intravenous formulation of CUDC-101, including a phase I dose escalation clinical trial of CUDC-101 in 25 patients with advanced, refractory solid tumors and a phase I expansion trial that tested CUDC-101 in 46 patients with specific tumor types, including breast, gastric, head and neck, NSCLC or liver cancers. The phase I expansion trial was designed as an open-label study in which patients were treated with CUDC-101 at the maximum tolerated dose which was determined in the phase I dose escalation study to be 275 milligrams per meter squared of human body surface area (275 mg/m²). The

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

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

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

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

In August 2009, we granted a worldwide, exclusive royalty-bearing license to develop, manufacture, market and sell our HSP90 inhibitor technology, including Debio 0932, to Debiopharm. Debiopharm has assumed all development responsibility for Debio 0932 and Debiopharm or a Debiopharm licensee will incur all costs related to the development, registration and commercialization of products under the agreement.

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

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

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

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

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

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

The agreement is effective as of August 5, 2009, and unless terminated earlier will expire, on a country-bycountry 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 to use reasonable commercial efforts as set forth in the agreement, we may terminate the agreement on thirty days' written notice to Debiopharm unless Debiopharm cures such failure before the end of such thirty day period. Either party may terminate the agreement prior to its expiration subject to certain conditions, upon 90 days (or 45 days in the case of failure to make payment of amounts due under the agreement) prior written notice to the other party in the event of the material breach of any term or condition of the agreement by the other party, unless the breaching party has cured such breach by the end of the applicable cure period; and immediately upon written notice to the other party if the other party or its affiliate directly, or through assistance granted to a third party, challenges, whether as a claim, a cross-claim, counterclaim, or defense, the validity or enforceability of any of such party's patents before any court, arbitrator, or other tribunal or administrative agency in any jurisdiction.

### **Corporate Information**

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

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

### **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.

### **Intellectual Property**

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

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

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

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

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

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

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

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

### **Research and Development Program**

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

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

### **Regulatory Matters**

FDA Requirements for New Drug Compounds

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

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

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

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

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

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

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

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

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

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

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

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

#### Foreign Regulation of New Drug Compounds

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

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

#### Hazardous Materials

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

#### Competition

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

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

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

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

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

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

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

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

#### Manufacturing

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

#### Sales and Marketing

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

#### **Employees**

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

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

Our executive officers are as follows:

Name	Age	Position
Daniel R. Passeri, MSc., J.D.	52	Chief Executive Officer
Ali Fattaey, Ph.D	48	President and Chief Operating Officer
Michael P. Gray	42	Chief Financial Officer
Mark W. Noel	54	Vice President, Technology Management and Intellectual Property
Maurizio Voi, M.D	55	Chief Medical Officer and Chief Development Officer
Daniel R. Passeri, MSc., J.D	Sept	Passeri has served as our Chief Executive Officer and as a director since ember 2001 and additionally held the title of President from September 2001 chruary 2013. From November 2000 to September 2001, Mr. Passeri served as

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.

#### Name

#### Age Position

Ali Fattaey, Ph.D . . . . . . . .

From February 2013, Dr. Fattaey has served as our President and Chief Operating Officer. From 2011 until February 2013, Dr. Fattaey served as the President and Chief Executive Officer of ACT Biotech, Inc., a biotechnology company. Dr. Fattaey served as ACT Biotech's Chief Operating and Scientific Officer from 2008 until 2010. From June 2006 until January 2008, Dr. Fattaey served the Director of Science and Technology at the Melanoma Therapeutics Foundation, a non-profit organization. From January 2005 until June 2006, Dr. Fattaey was a strategic consultant for pharmaceutical and biotechnology companies. Dr. Fattaey was previously employed at Sagres Discovery as its Chief Scientific Officer from November 2001 until April 2004 and subsequently as the Senior Vice President of Discovery Research at Chiron Corporation following Chiron's acquisition of Sagres Discovery. Dr. Fattaey was employed by Onyx Pharmaceuticals from January 1994 until June 2001, most recently as its Vice President of Discovery Research. Dr. Fattaey received his Ph.D. in microbiology from Kansas State University in 1989 and was a Research Fellow in Medicine at Harvard Medical School, Massachusetts General Hospital Cancer Center.

Michael P. Gray . . . . . . . .

Mr. Gray has served as our Chief Financial Officer since December 2006 and additionally held the title of Chief Operating Officer from December 2006 to February 2013. From December 2003 until December 2006, Mr. Gray served as our Vice President of Finance and Chief Financial Officer and served as our Senior Director of Finance and Controller from August 2000 until December 2003. From January 1998 to July 2000, Mr. Gray was Controller at Reprogenesis, Inc., a predecessor biotechnology company. Mr. Gray previously served as an audit professional for the accounting and consulting firm of Ernst & Young, LLP. Mr. Gray is a certified public accountant, holds an M.B.A. from the F.W. Olin Graduate School of Business at Babson College, and has a B.S. in accounting from Bryant College.

Mark W. Noel...

Mr. Noel has served as our Vice President, Technology Management and Intellectual Property since September 2008. From March 2001 until September 2008, Mr. Noel has served as our Vice President, Technology Management and Business Development. From March 2000 to February 2001, Mr. Noel was employed by GeneLogic, as Vice President of Customer Relations. From January 1998 to February 2000, Mr. Noel was employed by GeneLogic as Senior Director of Program Management. From December 1993 to January 1998, Mr. Noel was employed by the U.S. Department of Human Services National Cancer Institute Office of Technology Development (now the NCI Technology Transfer Center), where from July 1997 to January 1998, he served as Acting Deputy Director. From February 1989 to November 1993, Mr. Noel worked as a patent agent at Gist Brocades NV, a supplier of ingredients to the pharmaceutical and food sectors. Mr. Noel holds a B.S. in Chemistry from the University of Maryland.

Maurizio Voi, M.D ......

Dr. Voi has served as our Chief Medical and Chief Development Officer since November 2011. From October 2009 until November 2011, Dr. Voi was employed by Pfizer, Inc., a pharmaceutical company, as Vice President of Clinical Development and Medical Affairs at the Oncology Business Unit of Pfizer's Global Research and Development site in New York. Dr. Voi joined Pfizer in November 2009 as Thoracic Tumor Strategy Team Leader for Oncology. Prior to joining Pfizer, Dr. Voi served from 1998 to 2009 in several key positions at Bristol-Myers Squibb Company, a pharmaceutical company, most recently as the Executive Director, Global Clinical Development and Medical Affairs, Oncology. From 1987-1999, he served in several roles at Eli Lilly and Company, a pharmaceutical company. Dr. Voi holds an M.D. from the University of Padua, School of Medicine in Italy and practiced medicine at the General Hospital, Dolo in Venice, Italy.

#### ITEM 1A. RISK FACTORS

#### RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING

We have incurred substantial losses, expect to continue to incur substantial losses for the foreseeable future and may never generate significant revenue or achieve profitability.

As of December 31, 2012, we had an accumulated deficit of approximately \$748,505,000. We have incurred net losses of \$16,417,000, \$9,859,000, and \$4,435,000 for the years ended December 31, 2012, 2011 and 2010, respectively. Other than Erivedge, which was approved by the FDA in January 2012 for the treatment of advanced forms of BCC, we have not successfully commercialized any products to date, either alone or in collaboration with others. In December 2012, we, through our subsidiary Curis Royalty, received a \$30,000,000 loan pursuant to a credit agreement with BioPharma-II. Under the terms of the credit agreement, our right to certain future royalty and royalty-related payments on the commercial sales of Erivedge will be transferred by Curis Royalty to BioPharma-II to repay the loan. As a result, for the foreseeable future, we will only receive royalties under our collaboration agreement with Genentech to the extent net sales are generated at a level sufficient to derive royalties in excess of Curis Royalty's obligation to transfer such royalties to BioPharma-II, as only royalties received by Curis Royalty that are in excess of this obligation can be transferred to Curis from Curis Royalty. All of our drug candidates other than Erivedge are in early stages of development. For the foreseeable future, we will need to spend significant capital in an effort to develop and commercialize products and we expect to incur substantial operating losses. Our failure to become and remain profitable would, among other things, depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our research and development programs or continue our operations.

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

We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for substantial working capital to support our research and development activities principally for CUDC-427, CUDC-907, CUDC-101 and other drug candidates that we may seek to develop in the future, either from our internal discovery efforts or through acquisition from third parties, and to fund our general and administrative costs and expenses.

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

- up-front license payments and research and development funding that we may receive if we are able to successfully enter into new collaboration agreements for our technologies under development;
- contingent cash payments that we may receive for the achievement of development objectives under any new collaborations or our existing collaborations with Genentech, Debiopharm and LLS; and
- royalty payments that are contingent upon the successful commercialization of products based upon
  these collaborations, including royalties on sales of Erivedge in advanced BCC by Genentech, if any,
  that exceed the obligation to transfer certain royalties to BioPharma-II, which is approved in the U.S.
  and is under review for approval in Europe, Australia and other territories by the respective health
  authorities.

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

We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at December 31, 2012 should enable us to maintain current and planned operations into mid-2015. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may affect our planned future capital requirements and accelerate our need for additional working capital, many of which are outside our control, including the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our drug candidates;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators, including the level of any royalty payments from sales of Erivedge;
- the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates, including the level of any royalty payments from sales of Erivedge;
- unplanned costs to prepare, file, prosecute, maintain and enforce patent claims and other patent-related costs, including litigation costs and technology license fees; and
- unexpected losses in our cash investments or an inability to otherwise liquidate our cash investments due to unfavorable conditions in the capital markets.

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

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

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

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one
  or more of our drug candidates; or
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities, either internally or through third parties, or other activities that may be necessary to commercialize our drug candidates.

We transferred and encumbered certain royalty and royalty-related payments on the commercial sales of Erivedge in connection with our credit agreement with BioPharma-II and, as a result, we could lose all rights to future royalty and royalty-related payments.

In December 2012, through Curis Royalty, we received a \$30,000,000 loan pursuant to a credit agreement with BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that we receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to

permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to Curis.

Per the terms of the credit agreement, neither Curis nor Curis Royalty guaranteed any level of future royalty or royalty-related payments or the value of such payments as collateral to the loan. However, in certain circumstances, the obligations of Curis Royalty under the credit agreement to repay the loan may be accelerated, including:

- if any payment of principal is not made within three days of when such payment is due and payable or otherwise made in accordance with the terms of the credit agreement;
- if any representations or warranties made in the credit agreement or any other transaction document proves to be incorrect or misleading in any material respect when made;
- if there occurs a default in the performance of affirmative and negative covenants set forth in the credit agreement or under certain ancillary transaction documents;
- the failure by Genentech to pay material amounts owed under the collaboration agreement with Genentech because of an actual breach or default by Curis under the collaboration agreement;
- a material breach or default by Curis Royalty under certain ancillary transaction documents, in each
  case, which breach or default is not cured within 30 days after written demand thereof by BioPharma-II;
- the voluntary or involuntary commencement of bankruptcy proceedings by either Curis or Curis Royalty and other insolvency related defaults;
- any materially adverse effect on the binding nature of any of the transaction documents or the Genentech collaboration agreement;
- if any person shall be designated as an independent director of Curis Royalty other than in accordance with its limited liability company operating agreement; or
- if Curis shall at any time cease to own, of record and beneficially, 100% of the equity interests in Curis Royalty.

If any of the above were to occur, Curis Royalty may not have sufficient funds to pay the accelerated obligation and BioPharma-II could foreclose on the secured royalty and royalty-related payment stream. In such an event, we might lose our right to royalty and royalty-related payments not transferred to BioPharma-II, including those we would otherwise be entitled to receive if, or when, Curis Royalty satisfied its obligations to BioPharma-II under the credit agreement.

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

We may seek additional funding through public or private financings of debt or equity. For example, in June 2011 we entered into an At Market Issuance Sales Agreement, or ATM agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which, from time to time, we may offer and sell up to \$20 million of common stock that was registered pursuant to our universal shelf registration statement through MLV pursuant to one or more "at the market" offerings. In addition, with our prior written approval, MLV may also sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. The market for emerging life science stocks in general, and the market for our common stock in particular, is highly volatile. Due to this and various other factors, including adverse general market conditions, the early-stage status of our development pipeline and the early stage of the commercial U.S. launch of Erivedge, additional funding may not be available to us on acceptable terms, if at all, and we may not be able to sell additional shares under the arrangement with MLV at favorable prices, if at all. In addition, the terms of any financing may be dilutive or otherwise adversely affect other rights of our stockholders.

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

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

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

- the status of our preclinical and clinical development programs;
- the level of expenses incurred in connection with our preclinical and clinical development programs, including development costs relating to CUDC-427, CUDC-907 and CUDC-101;
- any intellectual property infringement lawsuit or other litigation in which we may become involved;
- the implementation of restructuring and cost-savings strategies;
- the implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, and non-recurring revenue or expenses under any such agreement; and
- compliance with regulatory requirements.

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

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

At December 31, 2012, we had \$58,701,000 of cash, cash equivalents, marketable securities and long-term investments consisting of cash, money market, commercial paper, corporate debt securities, and government obligations. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2012, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and liquidity of marketable securities owned by us.

There is a possibility that our stock price may decline due to the volatility of the stock market and the general economic downturn.

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

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

In January 2012, Erivedge was approved by the FDA as the first and only FDA-approved medicine for people with advanced BCC. Genentech and/or Roche have also filed regulatory submissions in several other territories seeking approval to commercialize Erivedge for this same indication. Genentech and Roche are also conducting a phase II clinical trial of Erivedge in operable nodular BCC and Erivedge is currently being tested in other cancers under collaborative agreements between Genentech and either third-party investigators or the NCI. Our near-term prospects substantially depend upon Genentech's ability to successfully develop and commercialize Erivedge in one or more indications and to demonstrate its safety and efficacy, as well as its superiority over existing therapies and standards of care. The development and commercialization of Erivedge could be unsuccessful if:

- Erivedge for the treatment of advanced BCC is not accepted as safe, efficacious, cost-effective, and preferable to current therapies in the medical community and by third-party payors;
- Genentech and/or Roche fails to apply the necessary financial resources and expertise to manufacturing, marketing and selling Erivedge for advanced BCC and to regulatory approvals for this indication outside of the U.S.;
- Genentech and/or Roche do not develop and implement effective marketing, sales and distribution strategies and operations, for development and commercialization of Erivedge for advanced BCC;
- Genentech and/or Roche do not develop, validate and maintain a commercially viable manufacturing process for Erivedge that is compliant with current good manufacturing practices;
- Genentech and/or Roche do not successfully obtain third party reimbursement and generate commercial demand that results in sales of Erivedge for advanced BCC in any geographic areas where requisite approvals have been, or may be, obtained;
- we or Genentech and/or Roche encounter any third party patent interference or patent infringement claims with respect to Erivedge;
- Genentech and/or Roche do not comply with any and all regulatory and legal requirements applicable to the sale of Erivedge for advanced BCC;
- new safety risks are identified after Erivedge is commercially marketed; and/or
- Erivedge does not demonstrate acceptable safety and efficacy in current or future clinical trials, or otherwise does not meet applicable regulatory standards for approval in indications other than advanced BCC.

In addition, pursuant to the terms of our credit agreement with BioPharma-II, for the foreseeable future we will only realize royalty revenue under our collaboration agreement with Genentech to the extent Genentech and Roche successfully commercialize Erivedge in the advanced BCC indication such that net sales are generated at a level sufficient to derive royalties in excess of the obligation to transfer such royalties to BioPharma-II.

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

Our targeted drug candidates, including CUDC-427, CUDC-907, CUDC-101 or Debio 0932, are novel compounds and their potential benefit as therapeutic cancer drugs is unproven. Our ability to generate revenues from these drug candidates, which we do not expect will occur in the short term, if ever, will depend heavily on

the successful development and eventual commercialization of our drug candidates. Continued development and eventual commercialization is subject to many potential risks. The drug candidates may not prove to be effective inhibitors of the cancer targets they are being designed to act against and may not demonstrate in patients any or all of the pharmacological benefits that may have been demonstrated in preclinical studies. The drug candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. If our drug candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. As a result of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop, enter into or maintain third party licensing or collaboration transactions with respect to, or successfully commercialize CUDC-427, CUDC-907, CUDC-101 or Debio 0932, or any other targeted drug candidates, in which case we will not achieve profitability and the value of our stock may decline.

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

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

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

We currently have a collaboration with Genentech pursuant to which we have granted to Genentech exclusive rights to develop and commercialize products based upon our Hedgehog pathway technologies. In January 2012, Genentech obtained FDA approval to commercialize Erivedge, the sole compound being developed under this collaboration, in advanced BCC. Genentech and Roche are also conducting, both alone and in collaboration, further studies of Erivedge for other indications. In addition, we entered into a license agreement with Debiopharm pursuant to which Debiopharm is testing Debio 0932 in a phase Ib clinical trial in advanced solid tumors and in a phase I/II clinical study in patients with advanced NSCLS. Debiopharm also has plans to initiate a phase I/II study in patients with renal cell carcinoma. Our collaboration agreement with Genentech and our license agreement with Debiopharm are our most significant collaborations, and these collaborations may not be scientifically or commercially successful due to a number of factors, including the following:

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

- Our agreements with Genentech and Debiopharm each permits the other party wide discretion in deciding which drug candidates to advance through the clinical trial process. It is possible for Genentech or Debiopharm to reject drug candidates at any point in the research, development and clinical trial process, without triggering a termination of the applicable agreement. In the event of any such decision, our business and prospects may be adversely affected and we may not have the commercial rights or the resources necessary to advance such programs on our own.
- We have granted clinical development rights to Genentech and Debiopharm, respectively, under our
  agreements with each of them. If they fail to allocate sufficient time, attention and resources to clinical
  trials of drug candidates under these collaborations, or fail to comply with good clinical practices or
  other applicable regulatory requirements for such clinical trials, the successful clinical development and
  commercialization of such drug candidates is likely to be adversely affected, as will our ability to
  generate revenue from such collaborations.
- Genentech or Debiopharm may develop and commercialize, either alone or with others, products that are similar to or competitive with the drug candidates that are the subject of its collaboration with us. For example, Genentech and Debiopharm each are seeking to develop several other cancer drug therapies.
- Genentech or Debiopharm may change the focus of its development and commercialization efforts or
  pursue higher-priority programs. Our ability to successfully commercialize drug candidates under
  collaboration with Genentech or Debiopharm could be limited if Genentech or Debiopharm decreases or
  fails to increase spending related to such drug candidates.
- Debiopharm may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or change of control. Any such transaction could divert the attention of our collaborative partner's management and adversely affect its ability to retain and motivate key personnel who are important to the continued development of the programs under such collaboration. In addition, an acquirer could determine to reprioritize our collaborator's development programs such that our collaborator ceases to diligently pursue the development of our programs, and/or terminates its collaboration with us. Genentech is a wholly-owned member of the Roche Group and as such is subject to the risk that Roche could determine to reprioritize Genentech's development programs which could reduce Genentech's efforts on the development or commercialization of Erivedge or cause Genentech to terminate our collaboration.
- Genentech or Debiopharm may, under specified circumstances, terminate its collaboration with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the scientific and financial communities.
- Both Genentech and Debiopharm have the first right to maintain or defend our intellectual property rights under their respective agreements and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators' acts or omissions.
- Genentech or Debiopharm may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.
- Genentech or Debiopharm may not comply with all applicable regulatory requirements, may select clinical investigators who are not qualified or who fail to comply with protocols or applicable regulatory requirements, or may fail to report safety data in accordance with all applicable regulatory requirements.
- 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 I or phase II clinical testing. For example, while we are not presently seeking to enter into corporate collaborations for any of our proprietary programs, we are likely to seek to partner CUDC-427, CUDC-907, and CUDC-101 as well as other drug candidates that we may develop internally or acquire from third parties in the future. We do not currently have the resources or capacity to advance these programs into later stage clinical development (i.e., phase III) or commercialization on our own. As such, our success will depend, in part, on our ability to enter into one or more such collaborations. We face significant competition in seeking appropriate collaborators and a number of recent business combinations among large pharmaceutical companies have resulted in a reduced number of potential future collaborators. In addition, collaborations are complex and timeconsuming to negotiate and document. Moreover, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for CUDC-427, CUDC-907, CUDC-101 or any future programs because our research and development pipeline may be insufficient, our programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy or sufficient differentiability compared to existing or emerging treatments. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us and such collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner or at all.

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

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

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

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

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

- preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results;
- we or any collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or terminate testing for a particular drug candidate;
- the results from preclinical studies and early clinical trials may not be statistically significant or
  predictive of results that will be obtained from expanded, advanced clinical trials;
- we may encounter difficulties or delays in manufacturing sufficient quantities of the drug candidate used in any preclinical study or clinical trial;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the timing and completion of clinical trials of our drug candidates depend on, among other factors, the
  number of patients required to be enrolled in the clinical trials and the rate at which those patients are
  enrolled, and any increase in the required number of patients, decrease in recruitment rates or
  difficulties retaining study participants may result in increased costs, program delays or program
  termination;
- our products under development may not be effective in treating any of the projected cancer indications
  or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may
  prevent or limit their commercial use;
- we, our clinical investigators, or our current or potential future collaborators and subcontractors, may
  fail to comply with applicable regulatory requirements, including GCPs and requirements regarding the
  disclosure of clinical trial information;
- institutional review boards, regulators, including the FDA or its foreign equivalents, or any collaborators
  may hold, suspend or terminate our clinical research or the clinical trials of our drug candidates for
  various reasons, including failure to achieve established success criteria, noncompliance with regulatory
  requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health
  risks; and
- we, along with any of our current or potential future collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA's Application Integrity Policy, or similar policy under foreign regulatory authorities, nor may we or any of our current or potential future collaborators or subcontractors use disqualified clinical investigators or institutions to perform clinical trials of our drug candidates. Employment or use of such a debarred or disqualified person or institution may result in delays in FDA's or foreign equivalent's review or approval of our products, or the rejection of data developed with the involvement of such person(s) or institution(s).

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

- be delayed in obtaining marketing approval for our drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended or with labeling that highlights undesirable safety risks;

- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements;
- · be subject to restrictions on how the product is distributed or used; or
- be unable to obtain reimbursement for use of the product.

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

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

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. In addition, many of our competitors have ongoing clinical trials for drug candidates that could be competitive with our drug candidates. Patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates or rely upon treatment with existing therapies that may preclude them from eligibility for our clinical trials.

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

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

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

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

We and our collaborators will be required to obtain regulatory approval in order to successfully advance drug candidates through the clinic and prior to marketing and selling such products. We have limited experience

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

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

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

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

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

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

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

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

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

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

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

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

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and
  willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in
  kind, to induce or reward either the referral of an individual for, or the purchase, order or
  recommendation of, any good or service, for which payment may be made under federally funded
  healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including

- mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, or the PPACA requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or
  marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental
  third-party payors, including private insurers, and some state laws require pharmaceutical companies to
  comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance
  guidance promulgated by the federal government in addition to requiring drug manufacturers to report
  information related to payments to physicians and other health care providers or marketing expenditures.

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

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

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

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

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

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

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

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the commencement and completion of preclinical studies, initiation and completion of clinical trials, and other developments and milestones under our proprietary programs and those programs being developed under collaboration agreements. Genentech is a wholly-owned member of the Roche Group and Roche has also made public statements regarding its expectations for the clinical development and potential regulatory approval of Erivedge in territories other than the U.S., and may in the future make additional statements about its goals and expectations for this collaboration with us. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in our and our current and potential future collaborators' preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by us and our current and potential future collaborators and the uncertainties inherent in the regulatory approval process. As a result:

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

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

### We face substantial competition, which may result in our competitors discovering, developing or commercializing products before or more successfully than we do.

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

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

Many of our competitors have substantially greater capital resources, research and development staffs and facilities, and more extensive experience than we have. As a result, efforts by other life science, medical device

and pharmaceutical companies could render our programs or products uneconomical or result in therapies superior to those that we develop alone or with a collaborator.

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

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

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

Product liability claims are inherent in the process of researching, developing and commercializing human health care products and could expose us to significant liabilities and prevent or interfere with the development or commercialization of our drug candidates. Regardless of their merit or eventual outcome, product liability claims would require us to spend significant time, money and other resources to defend such claims, could result in decreased demand for our future products or result in reputational harm and could result in the payment of a significant damage award.

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

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

We depend upon our senior management, including Daniel R. Passeri, our Chief Executive Officer, Ali Fattaey, Ph.D., President and Chief Operating Officer, Maurizio Voi, M.D., our Chief Medical and Chief Development Officer, and Michael P. Gray, our Chief Financial Officer. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of product development and other business objectives. Our officers all serve pursuant to "at will" employment arrangements and can terminate their employment with us at any time. We do not maintain key man life insurance on any of these officers. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to research, develop and successfully commercialize products in our areas of core competency.

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

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

We may seek to expand our operations, including without limitation through internal growth and/or the acquisition of businesses and technologies that we believe are a strategic complement to our business model. For example, we licensed CUDC-427 from Genentech in November 2012 for payments totaling \$9,500,000. We may not be able to identify suitable acquisition candidates or expansion strategies and successfully complete such acquisitions or successfully execute any such other expansion strategies. We may never realize the anticipated benefits of any efforts to expand our business. Furthermore, the expansion of our business, either through internal growth or through acquisitions, poses significant risks to our existing operations, financial condition and operating results, including:

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

Any business that we conduct in China will expose us to risks resulting from adverse changes in political, legal and economic policies of the Chinese government, which could impede our efforts in China and materially and adversely affect the development of our targeted cancer drug candidates.

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

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

### If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. Such estimates and judgments include the carrying value of our property, equipment and intangible assets, revenue recognition, the value of certain liabilities, including the fair value of our warrant liability, the repayment term of our loan with BioPharma-II and stock-based compensation expense. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates" elsewhere in this Annual Report on Form 10-K.

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our drug candidates may be delayed.

#### RISKS RELATING TO OUR INTELLECTUAL PROPERTY

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

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

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

The patent positions of pharmaceutical and life science companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions. The laws, procedures and standards that the U.S. Patent and Trademark Office and various foreign intellectual property offices use to grant patents, and the standards that courts use to interpret patents, are not always applied predictably or uniformly and have changed

in significant ways and are expected to continue to change. Consequently, the level of protection, if any, that will be obtained and provided by our patents if we attempt to enforce them, and they are challenged, is uncertain.

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

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

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

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

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

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

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

initiation of litigation or other proceedings against third parties to enforce our patent rights, to seek to
invalidate the patents held by these third parties or to obtain a judgment that our drug candidates do not
infringe the third parties' patents;

- participation in interference and/or derivation proceedings to determine the priority of invention if our competitors file U.S. patent applications that claim technology also claimed by us;
- initiation of opposition, reexamination, post grant review or inter partes review proceedings by third parties that seek to limit or eliminate the scope of our patent protection;
- initiation of litigation by third parties claiming that our processes or drug candidates or the intended use of our drug candidates infringe their patent or other intellectual property rights; and
- initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property that may be important to our business.

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

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

During the years ended December 31, 2012, 2011, and 2010, we conducted synthetic chemistry work through a contract research agreement with a medicinal chemistry provider in China. We seek to protect our intellectual property rights under this arrangement through, among other things, non-disclosure and assignment of invention covenants. Implementation and enforcement of Chinese intellectual property-related laws has historically been inconsistent and damages assessed may fail to reflect the true value of the infringed technology and its market. Accordingly, intellectual property rights and confidentiality protections in China may not be as effective as in the U.S. or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we might need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require significant expenditure of cash and management efforts and could harm our business, financial condition and results of operations. An adverse determination in any such litigation will impair our intellectual property rights and may harm our business, prospects and reputation.

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

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

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

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

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

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

#### RISKS RELATING TO MANUFACTURING AND SALES

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

We have no manufacturing experience or manufacturing capabilities. In order to continue to develop drug candidates, apply for regulatory approvals, and commercialize our products under development, we or any collaborators must be able to manufacture products in adequate clinical and commercial quantities, in compliance with regulatory requirements, including those related to quality control and quality assurance, at acceptable costs and in a timely manner. The manufacture of our drug candidates may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our drug candidates may make them prohibitively expensive.

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

Any contract manufacturers with whom we or our collaborators enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current good manufacturing practices or Quality System Regulation and other governmental regulations and corresponding foreign standards. Any failure by our or our collaborators' contract manufacturers, any collaborators, or us to comply with applicable regulations could result in sanctions being imposed, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of drug candidates, delays, suspension or withdrawal of approvals, imposition of clinical holds, seizures or recalls of drug candidates, operating restrictions and criminal prosecutions, any of

which could significantly and adversely affect our business. If we or a collaborator need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve any new manufacturers in advance. This would involve testing and pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.

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

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

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

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

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

We have no sales, marketing or product distribution experience. If we receive required regulatory approvals to commercialize any of our drug candidates, we plan to rely primarily on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, as part of our agreements with Genentech and Debiopharm, we have granted Genentech and Debiopharm the exclusive rights to distribute certain products resulting from such collaborations, and Genentech is currently distributing Erivedge as part of its U.S. commercialization rights following FDA approval of Erivedge in January 2012. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these additional arrangements on terms that are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

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.

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

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

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

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

#### RISKS RELATED TO OUR COMMON STOCK

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

The trading price of our common stock has been volatile and is likely to continue to be volatile in the future. For example, our stock traded within a range of a high price of \$5.65 and a low price of \$1.97 per share for the period January 1, 2011 through March 6, 2013. The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical and biotechnology company stocks. Prices for our stock will be determined in the marketplace and may be influenced by many factors, including:

- announcements regarding new technologies by us or our competitors;
- market conditions in the biotechnology and pharmaceutical sectors;
- rumors relating to us or our collaborators or competitors;
- litigation or public concern about the safety of our potential products;
- actual or anticipated variations in our quarterly operating results, including Erivedge royalty revenue that we receive from Genentech, and any subsequent restatement of such results;
- actual or anticipated changes to our research and development plans;
- deviations in our operating results from the estimates of securities analysts;

- entering into new collaboration agreements or termination of existing collaboration agreements;
- adverse results or delays in clinical trials being conducted by us or any collaborators;
- any intellectual property or other lawsuits involving us;
- third-party sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors or significant stockholders;
- · equity sales by us of our common stock to fund our operations;
- the loss of any of our key scientific or management personnel;
- FDA or international regulatory actions;
- the limited trading volume in our common stock; and
- general economic and market conditions, including recent adverse changes in the domestic and international financial markets.

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

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

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

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

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

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 June 2011 we entered into the ATM Agreement with MLV pursuant to which, from time to time, we may offer and sell up to \$20 million of the common stock that was registered on this shelf registration statement through MLV pursuant to one or more "at the market" offerings. In addition, with our prior written approval, MLV may also sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. Sales of substantial amounts of shares of our common stock or other securities under this registration statement could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities.

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

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

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

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

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

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

As of December 31, 2012, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 36% of our outstanding common stock. As a result, these stockholders, if acting together, will be able to exert influence over the management and affairs of our company and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or

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

We have anti-takeover defenses that could delay or prevent an acquisition that our stockholders may consider favorable or prevent attempts by our stockholders to replace or remove our current management and the market price of our common stock may be lower as a result.

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

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

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

#### ITEM 2. PROPERTIES

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

#### ITEM 3. LEGAL PROCEEDINGS

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

#### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

#### **PART II**

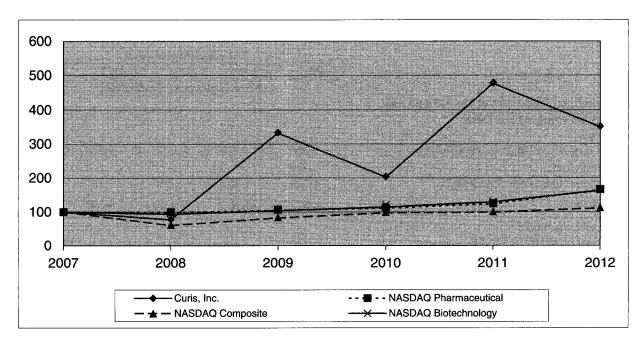
### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDERS MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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

- (b) *Holders*. On March 6, 2013, the last reported sale price of our common stock on the NASDAQ Global Market was \$3.24 and there were 241 holders of record of our common stock. The number of record holders may not be representative of the number of beneficial owners because many of the shares of our common stock are held by depositories, brokers or other nominees.
- (c) Dividends. We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, to support our business strategy and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the sole discretion of our board of directors after taking into account various factors, including our financial condition, operating results, capital requirements and any plans for expansion.
- . (d) Issuer Purchases of Equity Securities. We did not make any purchases of our shares of common stock in 2012.

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



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

#### 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,						
	2012	2008					
		(in thousa	nds, except per	share data)			
Consolidated Statement of Operations and Comprehensive Loss Data:							
Revenues:							
License and maintenance fees(1)	\$ 14,000	\$ 14,300	\$ 15,656	\$ 7,809	\$ 7,853		
Royalties	1,530 1,442	463	344		514		
Net revenues	16,972	14,763	16,000	8,590	8,367		
Costs and expenses:							
Cost of royalty revenues	176			_			
Research and development	15,493	13,693	11,373	9,933	13,226		
In-process research and development	9,500	<del></del>					
General and administrative	10,423	8,273	10,265	8,702	8,260		
Total costs and expenses	35,592	21,966	21,638	18,635	21,486		
Loss from operations	(18,620)	(7,203)	(5,638)	(10,045)	(13,119)		
Other income (expense):  Interest and other income	150	100	627	222	1,000		
Interest expense	(204) 2,257	(2,756)	 576		(4) —		
Total other income (expenses), net	2,203	(2,656)	1,203	222	996		
Net loss	\$ (16,417)	\$ (9,859)	\$ (4,435)	\$ (9,823)	\$ (12,123)		
Basic and diluted net loss per common share	\$ (0.21)	\$ (0.13)	\$ (0.06)	\$ (0.15)	\$ (0.19)		
Weighted average common shares (basic and							
diluted)	79,059	76,352	74,959	65,061	63,378		
		(in thousands) As of December 31,					
	2012	2011	2010	2009	2008		
Consolidated Balance Sheet Data:							
Cash, cash equivalents and investments	\$ 58,701	\$ 37,718	\$ 40,380	\$ 25,035	\$ 28,853		
Working capital	52,873	34,717	37,608	23,347	26,748		
Investment—restricted	194	236	497	216	210		
Total assets	69,768	48,180	50,649	36,099	39,982		
Long-term obligations(3)	31,522	4,518	1,656				
Accumulated deficit	(748,505) 34,267	(732,088) 39,876	(722,229) 45,518	(717,793) 33,052	(707,971) 37,225		
Total stockholders equity	57,207	37,010	75,510	55,052	31,443		

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

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

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

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

#### Overview

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

#### Erivedge®

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

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

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

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

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

Pursuant to the terms of our collaboration agreement with Genentech, we are entitled to a royalty on net sales of Erivedge that ranges from the mid-to-high single digits, and which escalates within this range with increasing product sales. The royalty rate applicable to Erivedge may be decreased to a low-to-mid single digit royalty in certain specified circumstances, including when a competing product that binds to the same molecular target as Erivedge is approved by the applicable regulatory authority and is being sold in such country by a third party for use in the same indication as Erivedge. In December 2012, through our wholly-owned subsidiary Curis Royalty, we entered into a \$30,000,000 debt transaction with BioPharma-II. The debt is secured with certain future royalties of Erivedge<sup>®</sup>. Pursuant to the terms of the credit agreement, Curis Royalty borrowed \$30,000,000 at an annual interest rate of 12.25% and upon closing, we transferred to Curis Royalty the right to receive certain royalty and royalty-related payments from the commercial sales of Erivedge under Curis' collaboration agreement with Genentech.

The loan from BioPharma-II will be repaid by Curis Royalty from the proceeds of the royalty and royalty-related payments that it receives from time to time from Genentech. Quarterly royalty and royalty-related payments from Genentech will first be applied to pay (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis' royalty obligations to university licensors, as described below, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by Curis enforcing its right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject to caps of \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$3,000,000 per quarter in 2015, will be applied first, to pay interest and second, principal on the loan. Curis Royalty will be entitled to receive and distribute to Curis remaining royalty and royalty-related amounts in excess of the foregoing caps, if any. In addition, if Erivedge royalties are insufficient to pay the accrued interest on the outstanding loan, unpaid interest will be added to the principal on a quarterly basis. As a result, we will continue to record royalty revenue from Genentech but expect the majority, if not all, of such revenues, subject to the above caps, will be used to pay down the loan received from BioPharma-II.

We are also obligated to make payments to university licensors on royalties that we earn in all territories other than Australia in an amount that is equal to 5% of the royalty payments that we receive from Genentech for a period of 10 years from the first commercial sale of Erivedge, which occurred in February 2012. For royalties that we would earn from Roche's potential future sales of Erivedge in Australia, we will be obligated to make payments to university licensors in an amount that is equal to 2% of Roche's direct net sales in Australia until April 2019, after which the amount will decrease to 5% of the royalty payments that we receive from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022.

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

### Targeted Cancer Drug Candidates

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

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

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

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

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

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

Debio 0932. In August 2009, we granted a worldwide, exclusive royalty-bearing license to develop, manufacture, market and sell our HSP90 inhibitor technology, including Debio 0932, to Debiopharm. Debiopharm has assumed all future development responsibility for Debio 0932 and Debiopharm or a Debiopharm licensee will incur all future costs related to the development, registration and commercialization of products under the agreement.

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

### Liquidity

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our corporate collaborators, the private and public placement of our equity securities, debt financings and the monetization of certain royalty rights. We have never been profitable on an annual basis and have an accumulated deficit of \$748,505,000 as of December 31, 2012. We expect that we will incur significant operating losses for the next several years as we seek to advance our research and development programs. Although Genentech recently received FDA approval to market Erivedge in the U.S., the level of future sales and the amount of resulting royalty revenue payable to us are both highly uncertain. In addition, in December 2012 we entered into a \$30,000,000 debt financing that is secured by Erivedge royalty revenues and for which up to \$4,000,000, \$8,000,000 and \$12,000,000 of our royalty revenues in 2013, 2014 and 2015 are required to be applied to debt repayments. For years after 2015, all royalty revenues that we receive will be applied to debt repayment until the debt is fully repaid. We currently estimate that the debt will be repaid by early 2017, but the actual timing of repayment will be dependent on the amount of royalty revenues that we earn on sales of Erivedge.

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

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

- Genentech's ability to successfully scale up the commercialization of Erivedge in advanced BCC in the U.S.;
- Genentech's and/or Roche's receipt of approval to commercialize Erivedge in advanced BCC in Europe
  and other territories including in Australia as well as its ability to successfully launch and
  commercialize Erivedge in these markets;
- positive results in Genentech's ongoing phase II clinical trial in patients with operable BCC;
- our ability to successfully plan, finance and complete current and planned clinical trials for CUDC-427, CUDC-907 and CUDC-101 and advance each drug candidate into phase II clinical testing;
- Debiopharm's ability to advance Debio 0932 into later stages of clinical development; and

• our ability to successfully enter into one or more material licenses or collaboration agreements for our proprietary drug candidates.

In the longer term, a key driver to our success will be our ability, and the ability of any current or future collaborator or licensee, to successfully commercialize drugs other than Erivedge based upon our proprietary technologies.

Our current collaboration and license agreements are summarized as follows:

Genentech Hedgehog Pathway Inhibitor Collaboration. Under the terms of the June 2003 agreement with Genentech, we granted Genentech an exclusive, global, royalty-bearing license, with the right to sublicense, to make, use, sell and import small molecule and antibody Hedgehog pathway inhibitors. Genentech subsequently granted a sublicense to Roche for non-U.S. rights to GDC-0449, other than in Japan where such rights are held by Chugai. Genentech and Roche have primary responsibility for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing. We are not a party to this agreement between Genentech and Roche but we are eligible to receive cash payments for regulatory filing and approval objectives achieved and future royalties on products developed outside of the U.S., if any, under our June 2003 collaboration agreement with Genentech.

The lead drug candidate being developed under this program is Erivedge, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor that is the first and only FDA-approved medicine for adults with advanced forms of basal cell carcinoma. Genentech and Roche are responsible for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing of Erivedge. We are eligible to receive cash payments for regulatory filing and approval objectives achieved and future royalties on products developed outside of the U.S., if any, under our June 2003 collaboration agreement with Genentech. We are eligible to receive up to \$115,000,000 in contingent cash payments for the development of Erivedge or another small molecule, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives, of which we have received \$46,000,000 to date. We are also eligible to receive royalties on sales of any Hedgehog pathway inhibitor products that are successfully commercialized by Genentech and Roche, for which we recognized \$1,530,000 in such revenue for sales of Erivedge during the year ended December 31, 2012. Future royalty payments related to Erivedge will service the outstanding debt and accrued interest to BioPharma-II, up to the quarterly caps for 2013, 2014 and 2015, and until the debt is fully repaid thereafter.

Genentech IAP Inhibitor License Agreement. In November 2012, we licensed from Genentech the exclusive, worldwide rights for the development and commercialization of CUDC-427, a small molecule that is designed to promote cancer cell death by antagonizing IAP proteins. Under the terms of the license agreement, we have the sole right and responsibility for all research, development, manufacturing and commercialization activities related to CUDC-427. During the fourth quarter of 2012, we incurred expenses of \$9,500,000 representing an up-front license payment and technology transfer costs payable to Genentech. In addition, Genentech is entitled to receive milestone payments upon the first commercial sale of CUDC-427 in certain territories and tiered single-digit royalties on net sales of CUDC-427.

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

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

### **Financial Operations Overview**

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

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

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

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

Under the terms of the loan, quarterly royalty and royalty-related payments from Genentech will first be applied to pay (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis' royalty obligations to academic institutions, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by Curis enforcing its right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject to caps of \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$3,000,000 per quarter in 2015, will be applied first, to pay interest and second, principal on the loan. Curis Royalty will be entitled to receive and distribute to Curis the remaining amounts above the caps, if any. Curis Royalty remains entitled to receive any royalty payments related to sales of Erivedge following repayment of the loan. Since the loan requires that up to \$4,000,000, \$8,000,000 and \$12,000,000 in royalty revenues are applied to pay interest and principal on the loan in 2013, 2014 and 2015, respectively, only royalty revenue in excess of these amounts, if any, will be available to fund our operations. No royalty revenues will be available for our use after 2015 until the loan is fully paid.

Per the terms of the credit agreement, neither Curis nor Curis Royalty guaranteed any level of future royalty or royalty-related payments or the value of such payments as collateral to the loan. However, in certain circumstances, the obligations of Curis Royalty under the credit agreement to repay the loan may be accelerated, including:

- if any payment of principal is not made within three days of when such payment is due and payable or otherwise made in accordance with the terms of the credit agreement;
- if any representations or warranties made in the credit agreement or any other transaction document proves to be incorrect or misleading in any material respect when made;
- if there occurs a default in the performance of affirmative and negative covenants set forth in the credit agreement or under certain ancillary transaction documents;
- the failure by Genentech to pay material amounts owed under the collaboration agreement with Genentech because of an actual breach or default by Curis under the collaboration agreement;
- a material breach or default by Curis Royalty under certain ancillary transaction documents, in each
  case, which breach or default is not cured within 30 days after written demand thereof by BioPharma-II;
- the voluntary or involuntary commencement of bankruptcy proceedings by either Curis or Curis Royalty and other insolvency related defaults;
- any materially adverse effect on the binding nature of any of the transaction documents or the Genentech collaboration agreement;
- if any person shall be designated as an independent director of Curis Royalty other than in accordance with its limited liability company operating agreement; or
- if Curis shall at any time cease to own, of record and beneficially, 100% of the equity interests in Curis Royalty.

If any of these conditions were to occur, Curis Royalty may not have sufficient funds to pay the accelerated obligation and BioPharma-II could foreclose on the secured royalty and royalty-related payment stream. In such an event, we might lose our right to royalty and royalty-related payments not transferred to BioPharma-II, including those we would otherwise be entitled to receive if, or when, Curis Royalty satisfied its obligations to BioPharma-II under the credit agreement.

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

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

We currently receive no research funding for our programs under our collaborations with Genentech, Debiopharm, and LLS and we do not expect to receive such funding in the future under these collaborations. Accordingly, our only source of revenues and/or cash flows from operations for the foreseeable future will be upfront license payments and funded research and development that we may receive under new collaboration agreements, if any, contingent cash payments for the achievement of clinical development and regulatory objectives, if any are met, under new collaborations or our existing collaborations with Genentech, Debiopharm, and LLS and royalty payments that are contingent upon the successful commercialization of any products based upon these collaborations. Our ability to enter into new collaborations and our receipt of additional payments under our existing collaborations with Genentech, Debiopharm, and LLS cannot be assured, nor can we predict the timing of any such arrangements or payments, as the case may be.

Cost of Royalty Revenues. Cost of royalty revenues consists of all expenses incurred that are associated with royalty revenues that we record in the Revenues section of our Consolidated Statements of Operations. These costs currently consist of payments we are obligated to make to university licensors on royalties that we earn from Genentech on net sales of Erivedge. In all territories other than Australia, our obligation is equal to 5% of the royalty payments that we receive from Genentech for a period of 10 years from the first commercial sale of Erivedge, which occurred in February 2012. For royalties that we would earn from Roche's future sales of Erivedge in Australia, if such approval is received, we will be obligated to make payments to university licensors in an amount that is equal to 2% of Roche's direct net sales in Australia until April 2019, after which the amount will decrease to 5% of the royalty payments that we receive from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022.

Research and Development. Research and development expense consists of costs incurred to discover, research and develop our drug candidates. These expenses consist primarily of: (1) salaries and related expenses for personnel including stock-based compensation expense; (2) outside service costs including, clinical research organizations and medicinal chemistry; (3) sublicense payments; and (4) the costs of supplies and reagents, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. We are currently incurring research and development expenses under our Hedgehog pathway inhibitor collaboration with Genentech related to the maintenance of third-party licenses to certain background technologies. In addition, we record research and development expense for payments that we are obligated to make to certain third-party university licensors upon our earning payments from Genentech related to the achievement of clinical development and regulatory objectives under our Hedgehog pathway inhibitor collaboration.

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

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

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

- the scope, quality of data, rate of progress and cost of clinical trials and other research and development activities undertaken by us or our collaborators;
- the results of future preclinical studies and clinical trials;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our drug candidates and any products that we may develop;
- the effect of competing technological and market developments; and
- the cost and effectiveness of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any of our drug candidates. Any failure to complete the development of our drug candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity.

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

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

## **Critical Accounting Policies and Estimates**

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

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

# Revenue Recognition

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

## License Fees and Multiple Element Arrangements.

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

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

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

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

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

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

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

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

- such milestone is commensurate with either of the following:
  - a) the vendor's performance to achieve the milestone (for example, the achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement); or
  - b) the enhancement of the value of the deliverable as a result of a specific outcome resulting from the vendor's performance to achieve the milestone (or substantive effort on our part is involved in achieving the milestone);
- such milestone relates solely to past performance; and
- the amount of the milestone payment is reasonable relative to all deliverables and payment terms in the arrangement.

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

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

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

Deferred Revenue. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Significant judgments are required in the application of revenue recognition guidance. For example, in connection with our existing and former collaboration agreements, we have historically recorded on our balance sheet short- and long-term deferred revenue based on our best estimate of when such revenue would be recognized. Short-term deferred revenue would consist of amounts that are expected to be recognized as revenue, or applied against future codevelopment 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 have adopted Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), Share-Based Payment, which generally requires that stock-based compensation transactions be accounted for using a fair-value-based method and is now referred to as FASB Codification Topic 718, Compensation – Stock Compensation.

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

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

## Fair Value Measurements

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

GAAP requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity

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 straightline method. Assumptions used in determining the term of the debt requires us to make significant judgments that would impact our operating results; however, we do not believe adjustments to the term of the debt and related amortization period would have a material impact on our financial statements.

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

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

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

## Results of Operations (all amounts rounded to the nearest thousand)

#### Years Ended December 31, 2012 and 2011

Revenues

Total revenues are summarized as follows:

<i>^</i>	For the Y Decem	Percentage Increase/		
	2012	2011	(Decrease)	
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 increased by \$2,209,000, or 15%, for the year ended December 31, 2012 as compared to the prior year, primarily related to royalty revenues of \$1,530,000 from sales of Erivedge during 2012. Erivedge was approved by the FDA for commercial sale in January 2012. In addition, we recognized revenues totaling \$1,000,000 under our agreement with LLS related to the achievement of clinical development objectives during 2012. We are eligible for additional milestone payments totaling \$3,000,000 over the term of our agreement with LLS, if our CUDC-907 program continues to successfully meet clinical development objectives.

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

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

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

# Operating Expenses

Research and development expenses are summarized as follows:

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

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

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

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

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

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

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

General and administrative expenses are summarized as follows:

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

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

Change in fair value of warrant liability. In connection with our January 2010 registered direct offering, we issued warrants to purchase an aggregate of 1,612,322 shares of common stock which became exercisable as of the closing of the transaction. The warrants have an initial exercise price of \$3.55 per share and have a five year term, and the fair value of the warrants is recorded as a long-term liability. The fair value of the warrants has been estimated using a Black-Scholes option pricing model under various probability-weighted outcomes which took into consideration the protective, but limited, cash-settlement feature for the benefit of the warrant holder that expired on January 27, 2012. The warrants are revalued each reporting period, with updated assumptions and the resulting gains and losses recorded as the change in fair value of warrant liability in the statement of operations. Expected volatilities used in the models were based on our historical volatility commensurate with the term of the warrants.

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

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

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

#### Other Expense (Income)

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

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

## Net Loss Applicable to Common Stockholders

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

## Years Ended December 31, 2011 and 2010

#### Revenues

Total revenues are summarized as follows:

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

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

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

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

#### **Operating Expenses**

Research and development expenses are summarized as follows:

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

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

General and administrative expenses are summarized as follows:

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

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

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

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

#### Other Income

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

### Net Loss Applicable to Common Stockholders

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

#### **Liquidity and Capital Resources**

Sources of Liquidity

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

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

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

terms of the loan, quarterly royalty payments from Genentech will first be applied to pay (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis' royalty obligations to academic institutions, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by Curis enforcing its right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject to caps of \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$3,000,000 per quarter in 2015, will be applied first, to pay interest and second, principal on the loan. We will be entitled to receive the remaining amounts above the caps, if any, and we remain entitled to receive any contingent payments upon achievement of clinical development objectives and royalty payments related to sales of Erivedge following repayment of the loan. The final maturity date of the loan will be the earlier of the date when the principal is paid in full and the termination of Curis Royalty's right to receive royalties under the collaboration agreement with Genentech.

At December 31, 2012, our principal sources of liquidity consisted of cash, cash equivalents, and investments of \$58,701,000, excluding our restricted investments of \$194,000. Our cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations. We maintain cash balances with financial institutions in excess of insured limits.

#### Cash Flows

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our office and laboratory, fees paid in connection with preclinical and clinical studies, laboratory supplies, consulting fees and legal fees. We expect that costs associated with clinical studies will increase in future periods assuming that CUDC-427, CUDC-907 and CUDC-101 advance into further stages of clinical testing.

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

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

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

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

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

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

### Funding Requirements

We have incurred significant losses since our inception. As of December 31, 2012, we had an accumulated deficit of approximately \$748,505,000. We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for working capital to support our research and development activities for CUDC-427, CUDC-907 and CUDC-101, and to fund our general and administrative costs and expenses.

We have historically derived a substantial portion of our operating cash flow from the research funding portion of collaboration agreements with third parties. However, we have no current research funding revenue under these agreements. Our ability to generate cash flow to operate our business will depend, in part, on royalty payments from the commercial sale of Erivedge and the ability of Erivedge to be approved for commercial sale in other countries, which would result in us becoming eligible to receive additional milestone payments as well as royalties on any future sales (subject to our obligation to transfer certain royalties to BioPharma-II pursuant to the terms of our credit agreement). We expect that our only source of cash flows from operations for the foreseeable future will be:

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

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

We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at December 31, 2012, should enable us to maintain current and planned operations into mid-2015. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing, many of which are outside our control, including the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our drug candidates;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators;
- the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates, including the level of any royalty payments from sales of Erivedge, which could increase the outstanding debt due to BioPharma-II if the royalty payments are insufficient to cover the accrued interest when payments are due;
- unplanned costs to prepare, file, prosecute, maintain and enforce patent claims and other patent-related costs, including litigation costs and technology license fees; and
- unexpected losses in our cash investments or an inability to otherwise liquidate our cash investments due to unfavorable conditions in the capital markets.

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

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

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

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

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

	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)	\$41,933	\$3,457	\$18,498	\$19,978	<b>\$</b>		
Operating lease obligations(2)	3,315	602	1,278	1,376	59		
Outside service obligations(3)	508	275	233		_		
Licensing obligations(4)	115	115					
Total future obligations	\$45,871	\$4,449	\$20,009	\$21,354	<u>\$59</u>		

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

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

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

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

#### Inflation

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

# **New Accounting Pronouncements**

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

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

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

Our current cash balances in excess of operating requirements are invested in cash equivalents, short-term marketable securities, which consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations with an average maturity of less than one year, and long-term investments. All marketable securities and long-term investments are considered available for sale. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. This objective may be adversely affected by the ongoing economic downturn and volatile business environment and continued unpredictable and unstable market conditions. Our marketable securities and long-term investments are subject to interest rate risk and will fall in value if market interest rates increase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, marketable securities or long-term investments since December 31, 2012, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities and long-term investments owned by us. To help manage this risk, we limit our investments to investment grade securities and deposits are with investment grade financial institutions. We believe that the realization of losses due to changes in credit spreads is unlikely as we currently have the ability to hold our investments for a sufficient period of time to recover the fair value of the investment and there is sufficient evidence to indicate that the fair value of the investment is recoverable. We do not use derivative financial instruments in our investment portfolio. We do not believe that a 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.

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

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

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

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of
  financial statements in accordance with generally accepted accounting principles, and that our receipts
  and expenditures are being made only in accordance with authorizations of management and our
  directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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

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

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

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

# Report of Independent Registered Public Accounting Firm

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

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

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

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

/s/ PRICEWATERHOUSECOOPERS LLP

Boston, Massachusetts March 13, 2013

# **Consolidated Balance Sheets**

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

# Consolidated Statements of Operations and Comprehensive Loss

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

# Consolidated Statements of Stockholders' Equity

	Common	ı Stock	Additional Paid-in	Treasury	Deferred	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Stock	Compensation	Deficit	Încome	Equity
Balance, December 31, 2009	68,360,067	\$683,601	\$751,068,635	\$(891,274)	\$(15,904)	\$(717,793,437)	\$ 637	\$ 33,052,258
Issuance of common stock in conjunction with the registered direct offering, net of issuance costs of \$1,310,000 and net of								
fair value of warrants of \$2,180,555		64,493	12,697,269	_	_	_		12,761,762
Issuances of common stock upon the exercise of warrants		17,427	1,760,097		<del></del>	_		1,777,524
Other issuances of common stock		2,518		_	_	_		349,576
Recognition of employee stock-based compensation		_	1,979,090	_		_		1,979,090
Mark-to-market on stock options to non-employees			(26,917)	· —	26,917	_		
Amortization of deferred compensation		_		-	(11,968)			(11,968)
Other comprehensive income		_					44,725	44,725
Net loss	_	_	*****			(4,435,310)		(4,435,310)
Balance, December 31, 2010	76,803,868	768,039	767,825,232	(891,274)	(955)	(722,228,747)	45,362	45,517,657
Issuances of common stock upon the exercise of warrants and stock options, for purchases under the ESPP, and pursuant to sales of shares under the Company's ATM agreement (see	1 2 (1 402	10.615	2.442.066					2 454 404
Note 10), net of \$128,155 in ATM issuance costs		13,615	2,442,866	_		_		2,456,481
Recognition of employee stock-based compensation		_	1,641,830	_				1,641,830
Mark-to-market on stock options to non-employees		_	129,326		955	_	(4.4.00%)	130,281
Other comprehensive loss			<del></del>	_	_	-	(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
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		2,000			<u></u>		_	964,000
Recognition of employee stock-based compensation		2,000	3,268,689					3,268,689
Mark-to-market on stock options to non-employees			355,222	_				355,222
Other comprehensive loss			333,222				(18,806)	(18,806)
Net loss		_	_			(16,416,907)		(16,416,907)
						(10,410,307)		(10,410,507)
Balance, December 31, 2012		\$ 810.655	\$782,837,507	\$(891.274)	\$ —	\$(748,504,549)	\$ 15,159	\$ 34,267,498
	======	====		<del>Ψ(0/1,2/4)</del>	Ψ	<del>Ψ(710,501,54</del> 2)	Ψ 13,139	<del></del>

# **Consolidated Statements of Cash Flows**

	Years Ended December 31,			
	2012	2011	2010	
Cash Flows from Operating Activities:				
Net loss	\$(16,416,907)	\$ (9,858,895)	\$ (4,435,310)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	126,537	107,396	686,495	
Stock-based compensation expense	3,623,911	1,772,111	1,967,122	
Issuance of common stock to licensees	964,000	<del>_</del>		
Change in fair value of warrant liability	(2,257,130)	2,756,426	(575,813)	
Amortization of debt issuance costs	5,769	246 122	(216.560)	
Non-cash interest (income)/expense	(434,763)	246,122	(316,560)	
Gain on sale of fixed assets and equipment		(77,068)	(98,107)	
Changes in operating assets and liabilities:  Accounts receivable	(865,997)	50,304	423,387	
Prepaid expenses and other assets	40,959	24,111	239,934	
Accounts payable and accrued and other liabilities	20,316	416,196	955,586	
Deferred revenue	20,510	.10,150	(475,833)	
Total adjustments	1,223,602	5,295,598	2,806,211	
Net cash used in operating activities	(15,193,305)	(4,563,297)	(1,629,099)	
Cash Flows from Investing Activities:				
Purchases of investments	(69,153,956)	(42,136,949)	(65,897,078)	
Sales of investments	46,214,044	51,834,854	51,464,558	
Net decrease/(increase) in restricted cash/investments	41,632	261,090	(281,002)	
Expenditures for property and equipment	(104,975)	(260,405)	(274,840)	
Proceeds from sale of fixed assets and equipment		77,068	99,160	
Net cash (used in) provided by investing				
activities	(23,003,255)	9,775,658	(14,889,202)	
Cash Flows from Financing Activities:				
Proceeds from issuance of common stock associated with	070 000	200.017	14040017	
offerings, net of issuance costs (see Note 10)	879,080	288,817	14,942,317	
Proceeds from issuance of common stock under the Company's share-based compensation plans and warrant				
exercises	5,105,699	1,792,003	2,127,100	
Payment of debt issuance costs	(160,240)	1,792,003	2,127,100	
Proceeds from issuance of debt	30,000,000		<del></del>	
Net cash provided by financing activities	35,824,539	2,080,820	17,069,417	
Net (decrease) increase in cash and cash equivalents	(2,372,021)	7,293,181	551,116	
Cash and cash equivalents, beginning of period	15,119,730	7,826,549	7,275,433	
Cash and cash equivalents, end of period	\$ 12,747,709	\$ 15,119,730	\$ 7,826,549	
Supplemental cash flow data related to non-cash items:				
Receivable for issuances of common stock	\$ 14,366	\$ 375,661	<u> </u>	
Unpaid debt issuance costs	\$ 261,475	\$	\$	
	<del></del>			

#### **Notes to Consolidated Financial Statements**

#### (1) OPERATIONS

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

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

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

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

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

upon, among other things, the success of its collaborations with Genentech, the Leukemia & Lymphoma Society, or LLS, and Debiopharm S.A., or Debiopharm, including its receipt of additional contingent cash payments under these collaborations; and its ability to control expenses and its ability to raise additional funds through equity or debt financings, new collaborations or other sources of financing. The Company may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations is highly uncertain. As a result, the Company may not be able to attain any further revenue under any collaborations or licensing arrangements. If the Company is unable to obtain adequate financing, the Company may be required to reduce or delay spending on its research and/or development programs.

#### (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## (a) USE OF ESTIMATES

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

#### (b) CONSOLIDATION

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

## (c) REVENUE RECOGNITION

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

# License Fees and Multiple Element Arrangements

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

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

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

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

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

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

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

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

#### Substantive Milestone Payments

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

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

- such milestone is commensurate with either of the following:
  - a) the vendor's performance to achieve the milestone (for example, the achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement); or
  - b) the enhancement of the value of the deliverable as a result of a specific outcome resulting from the vendor's performance to achieve the milestone (or substantive Company effort is involved in achieving the milestone);
- · such milestone relates solely to past performance; and
- the amount of the milestone payment is reasonable relative to all deliverables and payment terms in the arrangement.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and the resulting payment would be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above. In addition, the determination that one such payment was not a substantive milestone could prevent the Company from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable. Milestones that are tied to regulatory approval are not considered probable of being achieved until such approval is received. Milestones tied to counterparty 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 sales of Erivedge in the U.S. The Company expects to recognize royalty revenue in future quarters from Genentech's sales of Erivedge in the U.S. and in other markets where Genentech and Roche successfully obtain marketing approval, if any (see Notes 3(a) and 8). Royalty revenue is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and the Company has no remaining performance obligations under the arrangement. If royalties are received when the Company has remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and therefore would be recognized as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above.

## Deferred Revenue

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

#### Summary

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

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

#### (d) RESEARCH AND DEVELOPMENT

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

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

## (e) CASH EQUIVALENTS, MARKETABLE SECURITIES AND INVESTMENTS

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

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

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

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

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

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

	Amortized Cost	Unrealized Gain	Fair Value
U.S. Government obligations	\$ 3,808,641	\$ 63	\$ 3,808,704
•	8,787,778	1,363	18,789,141
Total marketable securities	\$22,596,419	\$1,426	\$22,597,845

# (f) FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company discloses fair value measurements based on a framework outlined by GAAP which requires expanded disclosures regarding fair value measurements. GAAP also defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

The FASB Codification Topic 820, Fair Value Measurements and Disclosures, requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be

required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. GAAP also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company's warrant liability was valued using a probability-weighted Black-Scholes model, discussed further in Note 10, and is therefore classified as Level 3.

In accordance with the fair value hierarchy, the following table shows the fair value as of December 31, 2012 and 2011 of those financial assets and liabilities that are measured at fair value on a recurring basis, according to the valuation techniques the Company used to determine their fair value. No financial assets or liabilities are measured at fair value on a nonrecurring basis at December 31, 2012 and 2011

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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	2 262 222			2 262 222
notes	2,263,323	1,825,000		2,263,323 1,825,000
Municipal bonds Short- and long-term investments	<del>_</del>	1,623,000		1,623,000
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	<u> </u>	\$	\$1,448,179	\$ 1,448,179
As of December 31, 2011:				
Cash equivalents				
Money market funds	\$ 5,366,747	\$ —	\$ —	\$ 5,366,747
Municipal bonds	2,375,000	_	_	2,375,000
Short-term investments		2 000 704		3,808,704
US government obligations	_	3,808,704	<del></del>	3,000,704
Corporate commercial paper, stock, bonds and notes	7,365,841	11,423,300		18,789,141
			<u> </u>	
Total assets at fair value	\$15,107,588	\$15,232,004	<u> </u>	\$30,339,592
Warrants			4,361,168	4,361,168
Total liabilities at fair value	<u> </u>	<u>\$</u>	\$4,361,168	\$ 4,361,168

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

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

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

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

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

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

#### (h) GOODWILL

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

## (i) TREASURY STOCK

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

## (i) BASIC AND DILUTED LOSS PER COMMON SHARE

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

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

## (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.

## (I) OPERATING LEASES

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

## (m) CONCENTRATION OF RISK

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

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

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

#### (n) COMPREHENSIVE LOSS

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

#### (o) NEW ACCOUNTING PRONOUNCEMENTS

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

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

#### (3) RESEARCH AND DEVELOPMENT COLLABORATIONS

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

#### (i) Agreement Summary

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

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

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

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

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

## (ii) Accounting Summary

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### (c) THE LEUKEMIA & LYMPHOMA SOCIETY AGREEMENT

## (i) Agreement Summary

In November 2011, the Company entered into an agreement under which The Leukemia & Lymphoma Society (LLS) agreed to support the Company's ongoing development of CUDC-907 for patients with relapsed or refractory lymphoma and multiple myeloma. Under the agreement, LLS will make milestone payments up to \$4,000,000 that are contingent upon the Company's achievement of specified clinical development objectives with CUDC-907.

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

- \$500,000 upon the Company's receipt of approval from an LLS oversight committee regarding the outcome of the Company's pre-IND correspondence with FDA;
- \$250,000 upon the Company's filing of an IND with the FDA and
- \$250,000 upon the first IRB approval for the initiation of a phase I trial.

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

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

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

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

# (ii) Accounting Summary

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

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

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

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

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

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

# (d) DEBIOPHARM AUGUST 2009 LICENSE AGREEMENT

#### (i) Agreement Summary

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

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

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

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

- a specified percentage of all sublicensing payments received by Debiopharm and its affiliates from sublicensees;
- a specified percentage of royalties Debiopharm and its affiliates receive from sublicensees; and
- a specified percentage of royalties on net sales of products by Debiopharm or its affiliates.

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

#### (ii) Accounting Summary

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

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

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

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

## (4) FORMER LICENSEES AND COLLABORATIONS

## (a) MICROMET SETTLEMENT

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

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

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

# 2010 Stock Incentive Plan

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

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

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

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

# Employee and Director Grants

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

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

The expected volatility is based on the annualized daily historical volatility of the Company's stock price through the end of the reporting period for a time period consistent with the expected term of each grant. Management believes that the historical volatility of the Company's stock price best represents the volatility of the stock price. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the expected term of the respective grant. The Company does not anticipate declaring dividends in the foreseeable future.

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

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

## Non-Employee Grants

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

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

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

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

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

# 2010 Employee Stock Purchase Plan

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

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

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

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

## **Total Stock-Based Compensation Expense**

For the years ended December 31, 2012, 2011 and 2010, the Company recorded employee and nonemployee stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations and Comprehensive Loss:

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

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

# (6) PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

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

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

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

#### (7) ACCRUED LIABILITIES

Accrued liabilities consist of the following:

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

#### (8) **DEBT**

In December 2012, the Company, through its wholly-owned subsidiary, Curis Royalty, entered into a \$30,000,000 debt transaction at an annual interest rate of 12.25% collateralized with certain future Erivedge royalty and royalty-related payment streams with BioPharma-II. Under the terms of the loan, quarterly royalty payments from Genentech will first be applied to pay (i) escrow fees payable by the Company pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) the Company's royalty obligations to academic institutions, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by the Company enforcing its right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject to caps of \$1,000,000 per quarter in 2013, \$2,000,000 per quarter in 2014 and \$3,000,000 per quarter in 2015, will be applied first, to pay interest and second, principal on the loan. The Company will be entitled to receive the

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

Upon the closing of the transaction, the Company transferred to Curis Royalty, pursuant to a purchase and sale agreement between Curis and Curis Royalty, the right to receive Erivedge royalty and royalty-related payments due from Genentech as defined in the credit agreement, and BioPharma-II loaned to Curis Royalty \$30,000,000 that, together with accrued interest, will be repaid by Curis Royalty quarterly from the proceeds of these Erivedge royalty and royalty-related payments. The final maturity date of the loan will be the earlier of the date when the principal is paid in full and the termination of Curis Royalty's right to receive royalties under the collaboration agreement with Genentech. At any time after January 1, 2017, Curis Royalty may, subject to certain limitations, prepay the outstanding principal of the loan in whole or in part, at a price equal to 105% of the outstanding principal on the loan, plus accrued but unpaid interest. The obligations of Curis Royalty under the credit agreement to repay the loan may be accelerated upon the occurrence of an event of default as defined in the credit agreement.

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

In connection with the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty payments. The loan constitutes an obligation of Curis Royalty, and is non-recourse to the Company.

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

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

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

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

#### (9) COMMITMENTS

# (a) OPERATING LEASES

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

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

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

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

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,

2012		602,000
		627,000
2014		 •
2015		 651,000
2016		 676,000
2017		 700,000
Thereafter		 59,000
Total minimum pay	ments	 \$3,315,000

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

# (b) LICENSE AGREEMENTS

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

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

# (10) COMMON STOCK AND WARRANT LIABILITY

## 2011 At Market Issuance Sales Agreement

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

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

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

# 2010 Registered Direct Offering

On January 27, 2010, the Company completed a registered direct offering of 6,449,288 units with each unit consisting of (i) one share of the Company's common stock and (ii) one warrant to purchase 0.25 of one share of common stock at a purchase price of \$2.52 per unit. The Company received net proceeds from the sale of the units, after deducting offering expenses, of approximately \$14,942,317 during the year ended December 31, 2010.

In connection with this offering, the Company issued warrants to purchase an aggregate of 1,612,322 shares of common stock. As of December 31, 2012, warrants to purchase 238,805 shares of the Company's common stock have been exercised. The warrants have an initial exercise price of \$3.55 per share and a five-year term. The warrants include certain protective features for the benefit of the warrantholder, including an anti-dilution adjustment clause and a possible cash-settlement option in the event of a change of control until the later to occur of (i) two years from the date of original issuance of the warrant and (ii) the date upon which Genentech or Roche submits a new drug application (NDA) for Erivedge which occurred in September 2011. As such, the cash-settlement option upon a change of control expired on January 27, 2012 and has no additional value to the warrantholders.

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

As of December 21

	As of December 51,			
	2012	2011	2010	
Fair value of the warrants	\$ 1,488,179	\$4,361,168	\$1,604,742	
Expected term	2.1 years	3 years	3-4 years	
Risk-free interest rate	0.27%	0.4%	1-1.6%	
Volatility	58%	78%	77.1-91.5%	
Dividends	None	None	None	

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

# 2007 Private Placement Offering

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

## (11) INCOME TAXES

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

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

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

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

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

200p-012-013-01-01-01-01-01-01-01-01-01-01-01-01-01-	December 31,		
	2012	2011	
Deferred Tax Assets:			
Net operating loss carryforwards	\$ 67,737,000	\$ 70,767,000	
Research and development tax credit			
carryforwards	10,538,000	10,661,000	
Depreciation and amortization	490,000	175,000	
Capitalized research and development			
expenditures	27,269,000	22,820,000	
Impairment of investments	64,000	108,000	
Stock options	2,809,000	2,433,000	
Accrued expenses and other	707,000	1,823,000	
Total Gross Deferred Tax Asset	109,614,000	108,787,000	
Valuation Allowance	(109,614,000)	(108,787,000)	
Net Deferred Tax Asset	\$	\$ <u> </u>	

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

	December 31,			
	2012			2011
Deferred Tax Assets:				
Current deferred tax assets	\$	42,000	\$	45,000
Non-current deferred tax assets	10	9,572,000	10	8,742,000
Valuation Allowance	(10	9,614,000)	(10	8,787,000)
Net Deferred Tax Asset	\$		\$	**********

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

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

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

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

## (12) RELATED PARTY TRANSACTION

License Agreement

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

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

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

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

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

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

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

# Severance Agreement

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

# (13) RETIREMENT SAVINGS PLAN

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

# (14) SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

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

**Quarter Ended** 

		March 31, 2012		June 30, 2012	Sej	ptember 30, 2012	D	ecember 31, 2012
Revenues	\$1	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)	7	77,556,366	7	9,052,517	7	9,639,433	,	79,971,888
Weighted average common shares (diluted)	8	33,336,695	7	9,052,517	7	9,639,433	•	79,971,888
	Quarter Ended							
		March 31, 2011		June 30, 2011	Sej	ptember 30, 2011	D	ecember 31, 2011
Revenues	\$	133,538	\$	392,867	\$	147,122	\$	14,089,053
(Loss) income from operations	(	(5,332,310)	(	4,618,965)	(	4,816,335)		7,565,107
Net (loss) income	(	(6,800,151)	(	4,914,064)	(	4,206,555)		6,061,875
Net (loss) income per common share (basic)	\$	(0.09)	\$	(0.06)	\$	(0.05)	\$	0.08
Net (loss) income per common share (diluted)	\$	(0.09)	\$	(0.06)	\$	(0.05)	\$	0.07
Weighted average common shares (basic)	7	75,825,801	7	6,378,369	7	6,543,074	•	76,649,034
Weighted average common shares (diluted)	7	75,825,801	7	6,378,369	7	6,543,074	;	81,354,223

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

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

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

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

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

None.

## ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls & Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2012. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2012, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective.

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

Changes in Internal Control Over Financial Reporting

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

## ITEM 9B. OTHER INFORMATION

None.

#### PART III

# ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERANCE

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

#### ITEM 11. EXECUTIVE COMPENSATION

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

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

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

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

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

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

# **PART IV**

# ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements.

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Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2012, 2011 and 2010	77
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2012, 2011 and	
2010	78
Consolidated Statements of Cash Flows for the Years Ended December 31, 2012, 2011 and 2010	79
Notes to Consolidated Financial Statements	80

(a)(2) Financial Statement Schedules.

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

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

# **SIGNATURES**

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

CURIS, INC.

By: /s/ DANIEL R. PASSERI

Daniel R. Passeri

Chief Executive Officer

Date: March 13, 2013

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

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

# EXHIBIT INDEX

		Incorporated by Reference			
Exhibit No.	Description	Form	SEC Filing Date	Exhibit Number	Filed with this 10-K
	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	Certificate of Designations of Curis, Inc.	S-3(333-50906)	08/10/01	3.2	
3.3	Amended and Restated By-laws of Curis, Inc.	S-1(333-50906)	11/29/00	3.2	
3.4	Amendment to Amended and Restated By-laws of Curis, Inc.	8-K	09/24/07	3.1	
	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	
#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	

Incorporated by Reference

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

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

	ŧ		Incorporated by Reference		
Exhibit No.	<b>Description</b>	Form	SEC Filing Date	Exhibit Number	Filed with this 10-K
	Material contracts—Miscellaneous				
10.40	Placement Agent Agreement, dated January 22, 2010, by and among the Company, RBC Capital Markets Corporation and Rodman & Renshaw, LLC	8-K	1/22/10	1.1	
10.41	Form of Subscription Agreement, dated as of January 22, 2010, by and among the Company and the investors named therein	8-K	1/22/2010	10.1	
10.42	Form of Warrant, dated January 22, 2010, issued pursuant to the Subscription Agreement, dated as of January 22, 2010	8-K	1/22/2010	4.1	
10.43	At Market Issuance Sales Agreement, dated June 13, 2011, by and between the Company and McNicoll, Lewis & Vlak, LLC	8-K	06/13/11	1.1	
	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				
+101.SCH	XBRL Taxonomy Extension Schema Document				
+101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
+101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
+101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
+101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

<sup>#</sup> Indicates management contract or compensatory plan or arrangement.

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

<sup>+</sup> Furnished, not filed, herewith.

#### STOCKHOLDER INFORMATION

Curis, Inc. and Subsidiaries

#### **OFFICERS**

Daniel R. Passeri Chief Executive Officer

Ali Fattaey, Ph.D.

President and Chief Operating Officer

Michael P. Gray

Chief Financial Officer, Treasurer and Secretary

Maurizio Voi, M.D.

Chief Medical and Chief Development Officer

Mark W. Noel

Vice President, Technology Management and Intellectual Property

#### MARKET INFORMATION

Our common stock has traded on the NASDAQ Global Market since August 1, 2000. Our trading symbol is "CRIS." There were 241 shareholders of record as of March 6, 2013. 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:

FY 2012	HIGH	LOW
1st Quarter	\$5.65	\$4.20
2nd Quarter	\$5.49	\$4.40
3rd Quarter	\$5.51	\$3.83
4th Quarter	\$4.72	\$2.98
FY 2011	HIGH	LOW
1st Quarter	\$3.63	\$1.97
2nd Quarter	\$4.42	\$3.00
3rd Quarter	\$4.30	\$2.70
4th Quarter	\$4.72	\$2.87

# CORPORATE HEADQUARTERS

Curis, Inc. 4 Maguire Road Lexington, MA 02421 P: 617.503.6500 F: 617.503.6501

#### TRANSFER AGENT

Computershare 250 Royall Street Canton, MA 02021 Dedicated Phone Number: (Toll Free) 877-810-2248 www.computershare.com/investor

# BOARD OF DIRECTORS

Susan B. Bayh
Director,
Dendreon Corporation, Emmis
Communications, Inc.,
and Wellpoint, Inc.

Martyn D. Greenacre
Chairman of the Board,
Life Mist, L.L.C.;
Director, Acusphere, Inc. and Neostem, Inc.

Kenneth I. Kaitin, Ph.D.
Director of the Tufts Center for the
Study of Drug Development; Research
Professor at Tufts University
School of Medicine

Robert E. Martell, M.D., Ph.D.
Chief Medical Officer, Tesaro, Inc.;
Adjunct Associate Professor of Medicine at
the Tufts University School of Medicine

James R. McNab, Jr. Chairman and Chief Executive Officer, Palmetto Pharmaceuticals, Inc.

Daniel R. Passeri Chief Executive Officer, Curis, Inc.

Kenneth J. Pienta, M.D.
Donald S. Coffey Professor of Urology,
Professor of Oncology, and Pharmacology and
Molecular Sciences at the Johns Hopkins
University School of Medicine

Marc Rubin, M.D. Executive Chairman, Titan Pharmaceuticals, Inc.

James R. Tobin
Retired
Former President and Chief Executive
Officer, Boston Scientific Corporation

#### INDEPENDENT ACCOUNTANTS

PricewaterhouseCoopers LLP 125 High Street Boston, MA 02110 P: 617.530.5000 www.pwcglobal.com

#### LEGAL COUNSEL

Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109 P: 617.526.6000 www.wilmerhale.com

#### ANNUAL MEETING

The annual meeting of stockholders will be held at 10:00 a.m. on May 30, 2013, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street, Boston, MA 02109

# SEC FORM 10-K

A copy of our 2012 annual report on Form 10-K, without exhibits, is available without charge upon written request to:

Investor Relations Curis, Inc. 4 Maguire Road Lexington, MA 02421 info@curis.com

CAUTIONARY NOTE This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about Curis' financial results and expected cash life, the potential effectiveness of its technologies under development and other information pertaining to its various research and development programs, strategies, plans and prospects. Such statements may contain the words "believes", "expects", "anticipates", "plans", "seeks", "estimates" or similar expressions. These forward looking statements are not guarantees of future performance and involve risks and uncertainties that may cause Curis' actual results to be materially different from those indicated by such forward-looking statements. Actual results can be affected by a number of important factors including, among other things: adverse results in Curis' and its strategic collaborators' product development programs; difficulties or delays in obtaining or maintaining required regulatory approvals; Curis' ability to obtain or maintain required patent and other proprietary intellectual property protection; changes in or Curis' inability to execute its business strategy; the risk that Curis does not obtain required additional funding; unplanned cash requirements; risks relating to Curis' ability to enter into and maintain important strategic collaborations, including its ability to maintain its current Hedgehog pathway inhibitor collaboration agreement with Genentech; competitive risks; and other risk factors described under the caption "Risk Factors" in the accompanying Annual Report on Form 10-K and any subsequent reports filed by Curis with the Securities and Exchange Commission. In addition, any forward-looking statements represent Curis' views only as of the date of this Annual Report and should not be relied upon as representing its views as of any subsequent date. Curis disclaims any intention or obligation to update any of the forward-looking statements, whether as a result of new inform

