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

FORM 10-K

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

For the fiscal year ended December 31, 2011.

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

For the transition period from to .

Commission file number: 001-35347

Clovis Oncology, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**90-0475355**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2525 28th Street, Suite 100 Boulder, Colorado	**80301**
(Address of principal executive offices)	**(Zip Code)**

(303) 625-5000
(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common Stock par value $0.001 per share	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

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

Indicate by check mark 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	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

As of March 12, 2012, the aggregate market value of the registrant's common stock, par value $0.001 per share, held by non-affiliates of the registrant was approximately $227,694,020, based on the closing price of the registrant's common stock on the NASDAQ Global Market of $21.70 per share. The registrant has elected to use March 12, 2012 as the calculation date, as on June 30, 2011 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately-held concern.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of March 12, 2012 was 22,375,757.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2012 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2011, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated therein.

TABLE OF CONTENTS

PART I

This Annual Report filed on Form 10-K and the information incorporated herein by reference includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Annual Report on Form 10-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and industry change and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained herein.

Any forward-looking statements that we make in this Annual Report on Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

You should also read carefully the factors described in the "Risk Factors" section of this Annual Report on Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and our website.

Clovis Oncology® and the Clovis logo are trademarks of Clovis Oncology, Inc. in the United States and in other selected countries. All other brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "Clovis," the "Company," "we," "us," and "our" refer to Clovis Oncology, Inc.

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and seek to simultaneously develop, with partners, companion diagnostics that direct our product candidates to the patients that are most likely to benefit from their use. We are currently developing three product candidates for which we hold global marketing rights: CO-101, a lipid-conjugated form of the anti-cancer drug gemcitabine, which is in a pivotal study in a specific patient population for the treatment of metastatic pancreatic cancer; CO-1686, an orally available, small molecule epidermal growth factor receptor, or EGFR, covalent inhibitor that was the subject of an investigational new drug application accepted by the FDA in January 2012 and is entering clinical development for the treatment of non-small cell lung cancer, or NSCLC, in patients with activating EGFR mutations, including the initial activating mutations, as well as the primary resistance mutation, T790M; and rucaparib, also known as CO-338, an orally available, small molecule poly (ADP-ribose) polymerase, or PARP, inhibitor being developed for various solid tumors that is currently in Phase I/II clinical trials.

We believe that discovery productivity exceeds development capacity in oncology, and we have built our organization to meet the need for innovative patient-specific oncology drug development. To implement our strategy, we have assembled an experienced team with core competencies in global clinical development and regulatory operations in oncology, as well as conducting collaborative relationships with companies specializing in companion diagnostic development. As our product candidates mature, we intend to build our own commercial organizations in major global markets and contract with local distributors in smaller markets.

The most common anti-cancer drug therapies typically address cancers within a specific organ as a single disease as opposed to a collection of different disease subtypes, often resulting in poor response rates and minimal effect on overall survival. We believe the oncology community is increasingly recognizing that tumors in a particular organ have unique pathologic and molecular characteristics that may warrant different treatment strategies. By better understanding differences in tumor biology and underlying disease pathways, researchers are identifying biomarkers to guide development of targeted oncology therapies, with streamlined clinical trials, stratified patient populations and improved patient outcomes. We believe that targeted therapies and companion diagnostics offer a patient-tailored approach to the treatment of cancers with improved diagnosis and outcomes.

Our pipeline consists of the following three product candidates, each of which is being developed for selected patient subsets:

- **CO-101**-Our most advanced product candidate, CO-101, is currently in a pivotal clinical study comparing CO-101 to gemcitabine in patients with metastatic pancreatic cancer for use as an initial therapy recommended for treatment of the disease, or a so-called "first-line treatment". We expect to complete enrollment for this trial in the first quarter of 2012 and report top line results as to overall survival in the prespecified hENT1-low patient subset in the fourth quarter of 2012. CO-101 is a novel, patented, lipid-conjugated form of the anti-cancer drug gemcitabine that is designed to treat patients with pancreatic cancer whose tumors express low amounts of a membrane transporter protein on the surface of the cancer cell known as hENT1 and are thus expected to be resistant to standard gemcitabine-based therapy. Based on the published results of multiple studies assessing the correlation of hENT1 expression to survival outcomes in pancreatic cancer patients treated with gemcitabine, as well as the prospective hENT1 classification of the first 250 patients enrolled in our pivotal study of CO-101, we believe that approximately one-half to two-thirds of pancreatic cancer patients express low levels of hENT1, and thus derive little or no benefit from gemcitabine therapy. We have partnered with Ventana Medical Systems for the development and commercialization of a companion diagnostic for the assessment of hENT1 levels.
- **CO-1686**-Our second product candidate, CO-1686, is an orally available, small molecule covalent inhibitor of the cancer-causing mutant forms of EGFR for the treatment of NSCLC. Because CO-1686 targets both the initial activating mutations as well as the primary resistance mutation, T790M, it has the potential to treat NSCLC patients with EGFR mutations, both as a first-line treatment, or as a therapy recommended for patients when a first-line treatment has been ineffective, a so-called "second-line treatment". In January 2012, the FDA accepted our investigational new drug, or IND, application to begin clinical investigation of CO-1686. Initial Phase I/II studies of CO-1686 are expected to commence in the U.S. and Europe in the second quarter of 2012 and in Asia during the third quarter of 2012. We have designed an accelerated clinical development program for CO-1686, and if successful, have a goal of filing a New Drug Application, or NDA, for an initial indication within approximately four years of filing our IND. We have partnered with Roche Molecular Systems, Inc., or Roche, for the development and commercialization of a companion diagnostic for EGFR mutations.
- **Rucaparib**-Our third product candidate, rucaparib, also known as CO-338, is an orally available, small molecule PARP inhibitor being developed for use as monotherapy or in combination with chemotherapeutic agents for the treatment of various cancers. Rucaparib is currently in a dose ranging Phase I clinical trial in combination with carboplatin chemotherapy for the treatment of solid tumors. This program is supplemented by two investigator-sponsored trials of rucaparib for the treatment of breast and ovarian cancers. In the fourth quarter of 2011, we initiated a Phase I/II monotherapy study of the oral formulation to determine an appropriate dose and schedule for long term administration, and to then assess preliminary efficacy in breast and ovarian cancers, including in patients with germline mutations in BRCA genes.

Our Strategy

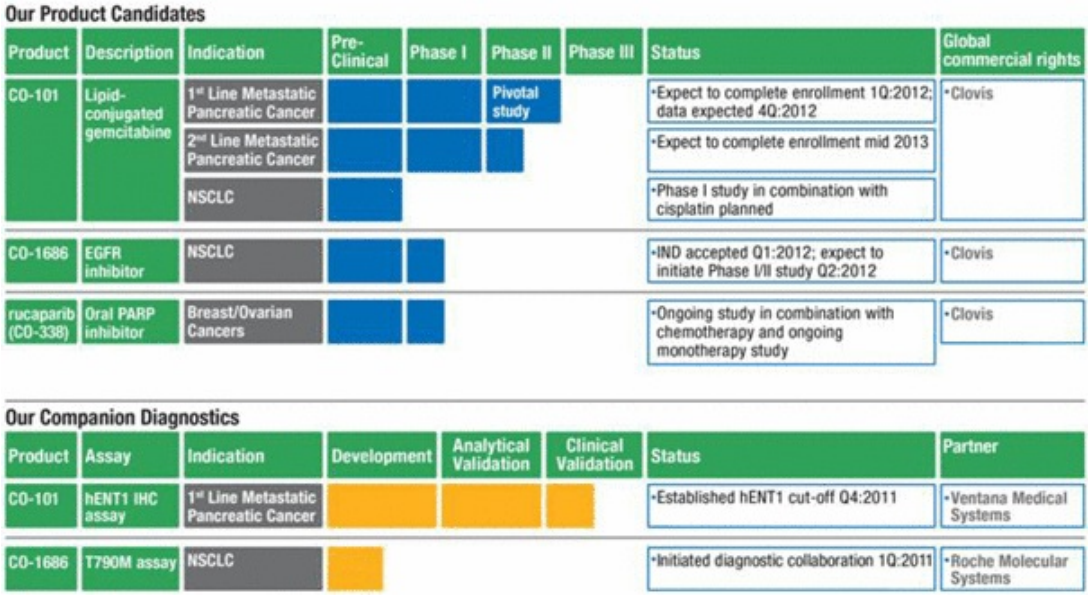
Our strategy is to acquire, develop, and commercialize innovative anti-cancer agents in the United States, Europe and additional international markets in oncology indications with significant unmet medical need. The critical components of our business strategy include the following:

- ***Focus on oncology***. The oncology market is characterized by a number of disorders with high rates of recurrence and a limited response from current therapies or treatments. Many of these therapies include severe side effects. New oncology product candidates addressing unmet medical needs or providing superior safety profiles are frequently the subject of expedited regulatory reviews and, if approved, can experience rapid adoption rates. We believe that the increasing role of targeted therapies and companion diagnostics to identify selected patient subsets in oncology presents the potential for improved patient outcomes.
- ***Focus on compounds where improved outcomes are associated with specific biomarkers.*** Our licensing strategy to date has been to prioritize opportunities in which a strong biological hypothesis has been established linking a specific characteristic or biological state of a cell, or biomarker, with improved outcomes for the product candidate. As evidenced by the proliferation of studies focused on the biomarkers of specific cancers, significant progress has been made over the last several years in the identification of molecular targets and pathways that more narrowly specify the causes of cancer and the variation in responses to different therapies experienced by patient subsets with a particular cancer or tumor type. In certain cases, the underlying science has progressed to the point that subset patient populations deriving little or no benefit from existing therapies can be identified and targeted by newly developed therapies, such as our product candidates. We believe that the identification of such subsets, and the correlation of their specific characteristics to the drug under development, should increase the clinical benefit to targeted patients and the probability of success in our clinical trials. Such patient identification should also enable us to design clinical trials that may be completed more rapidly than has traditionally been the case, and, if successful, to achieve clinical outcomes for the targeted group that are sufficiently attractive to support the risk/benefit metrics of healthcare payors.
- ***Combine companion diagnostics with drug development efforts to realize superior clinical outcomes*** . A companion diagnostic is a test or measurement intended to assist physicians in making treatment decisions for their patients. Companion diagnostics do so by identifying the presence of biomarkers, and physicians use this information to select a specific drug or treatment to which their patient will most likely respond. Our development strategy is based on the premise that we can utilize effective companion diagnostics to identify different patient subsets who we believe will uniquely benefit from our product candidates. We are partnering to develop these companion diagnostics for use in the clinical development and ultimate commercial utilization of our product candidates. Because we do not develop diagnostics internally, we are able to select from among all available technologies when choosing a partner for our programs under development. This flexibility allows us to choose the most appropriate partner and diagnostic platform for each program under development and affords us the best chance of clinical success. We have partnered with experienced diagnostic companies that we believe have the ability and commitment to gain the required regulatory approvals and support global commercialization for these companion diagnostics.

- ***Manage and control global development activities and regulatory operations.*** We believe our development and regulatory experience enables us to devise time- and cost-efficient strategies to develop and obtain regulatory approvals for new drugs, and to identify the regulatory pathway that allows us to get a product candidate to market as quickly as possible. Unlike many early stage biotechnology and pharmaceutical companies that have development or regulatory capabilities only in the country in which they are located, we have assembled an experienced team with a successful track record at managing global clinical development activities, and with multinational expertise in obtaining regulatory approvals for new drugs and in maintaining compliance with the regulations governing the sales, marketing and distribution of pharmaceutical products. We believe we can manage a global development program without local partners. We manage critical functions in house, including clinical development, biostatistics, pharmaceutical development, molecular diagnostics and clinical and regulatory operations, and we outsource certain activities where economically and strategically appropriate.
- ***Seek and maintain global commercial rights.*** We believe that it is very important to maintain global rights to our product candidates, and that we can build our own commercial organizations in major pharmaceutical markets as well as a network of third-party distributors in smaller markets. We believe there are a relatively small number of oncologists practicing in each of the major pharmaceutical markets and an even smaller number of oncology opinion leaders who significantly influence the types of drugs prescribed in cancer therapy. We therefore believe that we can effectively reach the oncology markets with a relatively small sales and marketing organization focused on these physicians and oncology opinion leaders. As a result, we plan to maintain commercial autonomy and will not require a pharmaceutical partner for commercialization activities. By managing the global sales and marketing of our products on our own, we believe we can provide uniform marketing programs and consistent product positioning, pricing and labeling. Finally, by controlling commercial activities ourselves in major markets, we will retain the vast majority of the revenues from our product candidates.

Product Candidates

Consistent with our strategy, each of our initial three in-licensed product candidates, for which we hold global marketing rights, is being developed for selected patient subsets. The following table summarizes the status of our product pipeline:



CO-101—a Lipid-Conjugated form of the Anti-Cancer Drug Gemcitabine

Overview

CO-101 is a new chemical entity that we in-licensed in November 2009 from Clavis Pharma ASA, a publicly traded biotechnology company based in Oslo, Norway. CO-101 is a novel, patented, lipid-conjugated form of the anti-cancer drug gemcitabine. CO-101 is designed to treat patients with pancreatic cancer whose tumors express low amounts of a membrane transporter protein known as hENT1 and thus are expected to be resistant to standard gemcitabine-based therapy. CO-101 is currently in an international, randomized, controlled 360-patient Phase II clinical study comparing CO-101 to gemcitabine for the first-line treatment of metastatic pancreatic cancer. We expect to complete enrollment for this trial in the first quarter of 2012 and report top line results as to overall survival in the prespecified hENT1-low patient subset in the fourth quarter of 2012. While we have not sought a Special Protocol Assessment, or SPA, from the U.S. Food and Drug Administration, or FDA, for this trial, for the reasons set forth under "—Regulatory Strategy" below, we believe that if its results are positive, this study will serve as a pivotal trial for CO-101 and enable us to file a New Drug Application, or NDA, with the FDA and a Marketing Approval Application, or MAA, with the European Medicines Agency, or EMA, in mid-2013. We are also conducting clinical trials of CO-101 for the second-line treatment of pancreatic cancer.

Pancreatic Cancer Market Overview

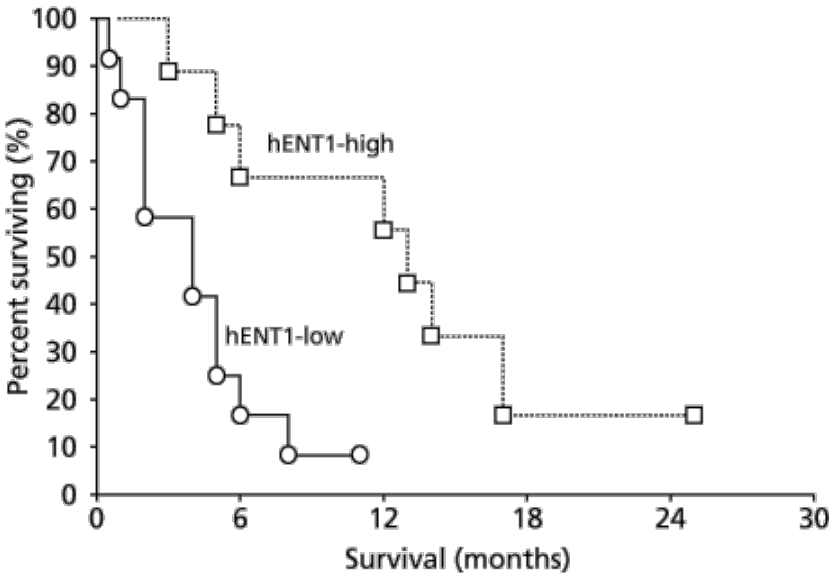
According to the American Cancer Society, over 43,000 new cases of pancreatic cancer occurred in the United States in 2010. In addition, according to Pancreatic Cancer Action Network, over 60,000 new cases are reported each year in the European Union and according to a study published in Cancer Chemotherapy and Pharmacology in 2004, over 20,000 new cases are reported annually in Japan. According to Medical, Surgical & Radiation Oncology (9th Edition, 2005), 85% of patients with pancreatic cancer present with unresectable, locally advanced, also referred to as Stage III, or metastatic, also referred to as Stage IV, disease. Even after surgical resection and adjuvant chemotherapy or radiotherapy for apparently localized disease, these patients often experience early recurrence and rapid disease progression. As a result, according to the American Cancer Society, pancreatic cancer has one of the highest mortality rates among all cancers, with estimates for one- and five-year overall survival of 24% and 5%, respectively, in the United States.

The standard first-line treatment for patients with unresectable or metastatic disease is gemcitabine, given as monotherapy. Gemcitabine was originally introduced in the United States in 1996 under the brand name Gemzar ®, and is now widely available as a generic drug. Gemcitabine is part of a class of drugs known as nucleoside analogues and can be used alone or in combination with other chemotherapy agents in the treatment of various malignancies, including pancreatic, NSCLC, breast, and ovarian cancers. Current guidelines of the National Comprehensive Cancer Network list gemcitabine monotherapy as an appropriate therapy for all pancreatic cancer patients eligible for cytotoxic therapy. Although the drug Tarceva ® (erlotinib) is approved in combination with gemcitabine in patients with metastatic pancreatic cancer, this combination involves increased toxicity and has been shown to confer a median survival benefit of only approximately two weeks when compared to gemcitabine monotherapy. Alternative therapies for the treatment of pancreatic cancer include: FOLFIRINOX (combination of 5-fluorouracil (5-FU), leucovorin, irinotecan and oxaliplatin), gemcitabine combination therapy or capecitabine. Some patients initially respond to cytotoxic chemotherapy, but all eventually progress, and many fail to derive even an initial benefit from such treatment. There are no approved second-line treatments for pancreatic cancer, and in practice, for those patients that do receive second-line treatment, it is typically a treatment that was not utilized in the first-line setting. Based upon a survey which we commissioned in 2009 of approximately 25 physicians in the United States and Europe, we believe that the consequence of this treatment paradigm is that approximately 80% of all pancreatic cancer patients will receive gemcitabine during their disease course.

Targeting Gemcitabine Non-Responders: the hENT1 Hypothesis

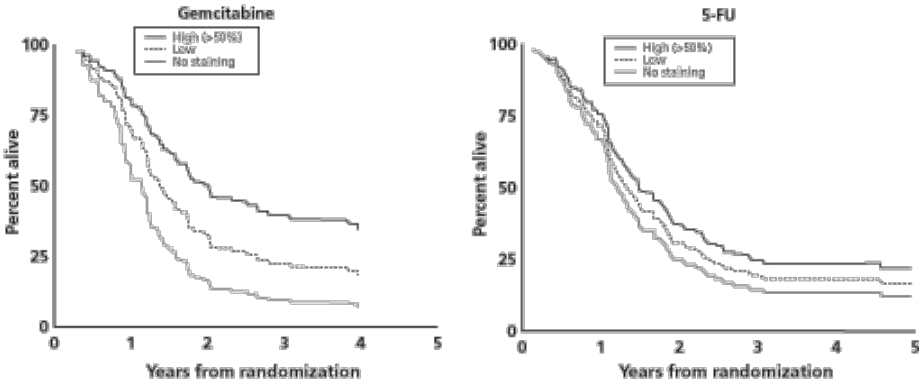
For gemcitabine to kill cancer cells, it must enter them through specific membrane transporters, or channels, on the surface of the cancer cells. The human equilibrative nucleoside transporter 1, or hENT1, is believed to be the dominant transporter for gemcitabine. As a consequence, it is believed that tumor cells with low hENT1 expression will be resistant to gemcitabine therapy. This was first supported by clinical data in 2004. Specifically, Clinical Cancer Research reported the study results of 21 metastatic pancreatic cancer patients treated with gemcitabine. This study demonstrated that survival after gemcitabine therapy was positively correlated with hENT1 expression. As shown in the figure below, also referred to as a Kaplan-Meier estimate of survival, patients with a high level of hENT1 expression had a median overall survival of 13 months compared to four months for those patients with a low level of hENT1 expression when treated with gemcitabine.

Kaplan-Meier estimate of survival in gemcitabine-treated hENT1-high and hENT1-low pancreatic cancer patients.



*hENT1-high = all tumor cells had detectable hENT1 protein by IHC
Source:Spratlin et al. Clin Can Res(2004)

This correlation of overall survival and hENT1 expression in pancreatic cancer patients treated with gemcitabine has been further demonstrated in multiple studies. For example, in 2009, a study published in Gastroenterology reported the results of a retrospective analysis of randomized samples collected from 198 pancreatic cancer patients between 1998 and 2002 comparing treatment with gemcitabine versus 5-FU. Patients in this study treated with gemcitabine who had a high level of hENT1 expression had a median overall survival of 21 months, compared to a median overall survival of 16 months for gemcitabine-treated patients with low hENT1 expression and 12 months for gemcitabine-treated patients with no hENT1 expression. Importantly, the results of this study also demonstrated that there was no correlation between overall survival and hENT1 expression for patients treated with 5-FU. This suggests that the correlation between survival and hENT1 expression is specific to pancreatic cancer patients treated with gemcitabine and not a prognostic marker. The Kaplan-Meier curves for this study are shown in the figure below.



Source: Farrell et al. Gastroenterology 2009:136:187-195

A positive, and statistically significant association is seen between tumor hENT1 expression and overall survival for recipients of gemcitabine (left, p=0.002 for high vs. no hENT1, p=0.03 for low vs. no hENT1), but not for recipients of 5-FU (right, p=not significant). hENT1 expression was characterized as no, low or high. "High hENT1" was defined by strong reactivity in greater than 50% of neoplastic cells on IHC, whereas "no hENT1" was defined as no staining in greater than 50% of neoplastic cells. A score of low hENT1 staining was given to all cases in between.

The table below summarizes a number of studies conducted over the past several years that have repeatedly confirmed the correlation between survival outcomes for pancreatic cancer patients treated with gemcitabine and their hENT1 expression and repeatedly found distributions of pancreatic cancer patients with low expressions of hENT1 ranging from 40% to 60% of all pancreatic cancer patients.

Study Author	Year	Number of Patients by hENT1 status	Median Overall Survival by hENT1 status (months)	P-value(s)
Spratlin	2004	High: 9 Low: 12	High: 13 Low: 4	0.01
Giovanetti	2006	High: 37 Low: 44	High: 22 Low: 12	<0.001
Farrell	2009	High: 34 Low: 39 No hENT1: 18	High: 21 Low: 16 No hENT1: 12	0.002 0.03
Morinaga	2011	High: 16 Low: 11	High: 22 Low: 12	0.02
Marechal	2011	High: 80 Low: 129	High: 51 Low: 24	<0.001

In the Spratlin study, samples defined as hENT1-high had uniformly detectable hENT1 and samples defined as hENT1-low had 10-100% of tumor cells without detectable hENT1. In the Giovanetti study, a median hENT1 expression was established based on gene expression levels, and samples with hENT1 expression over the median were defined as hENT1-high and samples with hENT1 expression under the median were defined as hENT1-low. In the Farrell study, hENT1-high was defined by strong reactivity in greater than 50% of neoplastic cells on IHC, no hENT1 was defined as no staining in greater than 50% of neoplastic cells and hENT1-low was defined as all cases in between. In the Morinaga study, a median hENT1 expression was established based on an assessment of intensity of sample staining and the percentage of positive tumor cells, and samples with hENT1 expression over the median were defined as hENT1-high and samples with hENT1 expression under the median were defined as hENT1-low. In the Marechal study, a median hENT1 expression was established based on an assessment of intensity of sample staining, and samples with hENT1 expression over the median were defined as hENT1-high and samples with hENT1 expression under the median were defined as hENT1-low.

These studies were conducted independently of each other with different personnel, methodologies, criteria and protocols, including different definitions of hENT1 expression. Indeed, as is described below, one of the principal concepts underlying the LEAP clinical trial was our decision to arrive at our own definition of a low level of hENT1 expression, based upon our retrospective analysis of existing tissue samples from other trials and using the companion diagnostic we have developed with Ventana, and to then apply this definition prospectively in our LEAP clinical trial.

CO-101: Addressing Patients with Low Levels of hENT1

CO-101, also known as gemcitabine-5'-elaidate, is a new chemical entity that is derived by adding a fatty acid to the gemcitabine chemical structure, creating a lipid-conjugate. In contrast to the conventional form of gemcitabine, the lipid-conjugate enables CO-101 to enter cancer cells without the need for a specific membrane transporter protein on the surface of the cancer cell known as hENT1, as evidenced by the accumulation of active drug metabolite inside cells with low hENT1 that are treated with CO-101. CO-101 is thus designed to address the unmet need of patients with pancreatic cancer whose tumors express low amounts of hENT1 and are thus expected to be resistant to standard gemcitabine-based therapy. Based on the published results of multiple studies assessing the correlation of hENT1 expression to survival outcomes in pancreatic cancer patients treated with gemcitabine, as well as the prospective hENT1 classification of the first 250 patients enrolled in our ongoing pivotal study of CO-101, we believe that approximately one-half to two-thirds of pancreatic cancer patients express low levels of hENT1. CO-101 has a broad spectrum of anti-proliferative activity in vitro and antitumor activity in a wide range of mouse and human tumor models in vivo. These tumor models are similar to those used for evaluating the in vivo activity of gemcitabine.

CO-101 Clinical Development

LEAP Study: Pivotal Trial of CO-101 in First-Line Pancreatic Cancer. In mid-2010, we commenced a pivotal study of CO-101, which we refer to as LEAP (**L**ow h**E**NT1 and **A**denocarcinoma of the **P**ancreas). We plan to enroll a total of 360 patients across approximately 90 sites in North and South America, Europe and Australia. This open-label, randomized, controlled, multicenter study compares CO-101 to gemcitabine as a first-line treatment in patients with metastatic pancreatic cancer. The primary objective of this study is to compare the overall survival of patients with metastatic pancreatic cancer and low hENT1 expression that are treated with CO-101 versus gemcitabine. Secondary endpoints include overall survival in all patients and in patients with high hENT1 expression, disease response rate, and drug tolerability and toxicity. Patients enrolled in the trial are being randomized on a one-to-one basis to receive either CO-101 or gemcitabine. Patients receiving CO-101 are dosed at 1250mg/m ^{2} delivered through intravenous infusion once per week for three out of every four weeks. Gemcitabine patients are dosed at its standard prescribing regimen of 1000mg/m ^{2} delivered through intravenous infusion once per week for seven weeks, followed by one week of rest and then once per week for three out of every four weeks. We expect enrollment to be completed in the first quarter of 2012. The study was designed to show that gemcitabine will have no better effect than best supportive care in hENT1-low patients, and that CO-101 will perform in hENT1-low patients similarly to the way gemcitabine does in hENT1-high patients. Since, according to its FDA approved prescribing information, gemcitabine has a median overall survival of 5.7 months in metastatic pancreatic cancer patients, we have designed the study to show a median survival of approximately 4 months for gemcitabine in hENT1-low patients, which is consistent with best supportive care, versus 7.7 months for CO-101 in hENT1-low patients. While multiple publications support this hypothesis, the LEAP trial is the first prospective test of this hypothesis. We expect to report top line overall survival data from this trial in the fourth quarter of 2012. While we have not sought an SPA from the FDA for this trial, we believe that if its results are positive, this study will serve as a pivotal trial for CO-101 and enable us to file a NDA with the FDA and a MAA with the EMA in mid-2013.

To test the primary hypothesis that CO-101 is more effective than gemcitabine in pancreatic cancer patients with low levels of hENT1, we needed to develop an in vitro diagnostic, or IVD, product to reliably measure tissue hENT1 expression and enable prospective classification of patients as either hENT1-high or hENT1-low. We are collaborating with Ventana Medical Systems, Inc., part of the Roche Group, or Ventana, to develop the IVD using an IHC based approach. Key characteristics of this companion diagnostic are:

- *Ability to analyze accessible tissue*: Patients with metastatic pancreatic cancer typically have liver metastases which can be biopsied quite easily and analyzed by IHC;
- *Simple assay/local analysis:* IHC is a standard laboratory technique that is widely utilized and does not require samples to be sent off-site for analysis;
- *Based on existing technology:* Ventana utilized established IHC diagnostic techniques to develop a validated hENT1 IHC assay using knowledge already gained from IHC hENT1 assays developed by academics;
- *Regulatory precedent:* IHC IVDs have previously been approved by the FDA as companion diagnostics for cancer therapeutics, including Ventana's PATHWAY HER-2/neu assay intended to assist in the assessment of breast cancer patients for whom Herceptin treatment is considered; and
- *Reimbursement*: IHC diagnostic kits are widely reimbursed by health care payors.

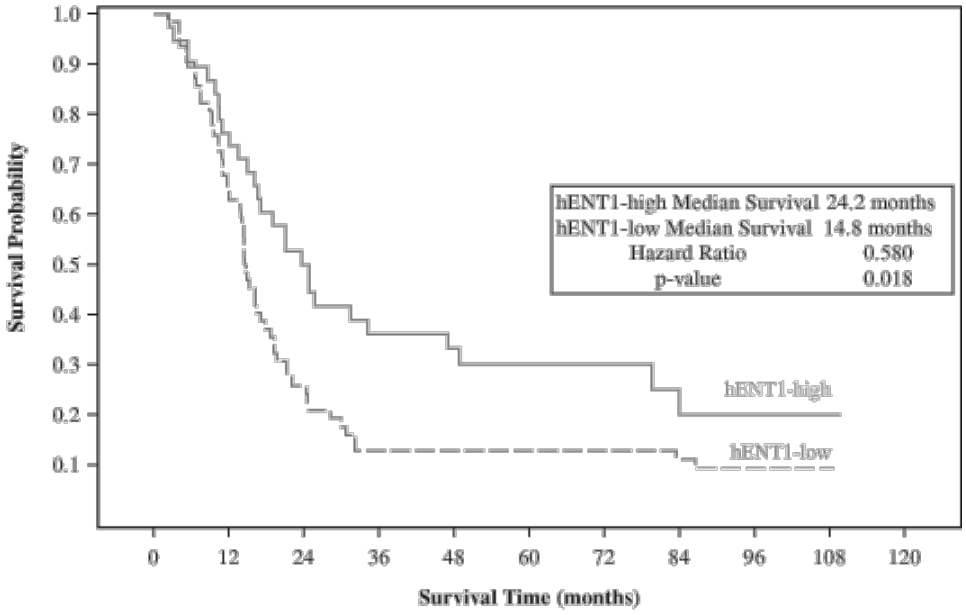
In the United States, the marketing approval of this type of IVD requires the submission to and approval by the FDA of a Pre-Market Approval Application, or PMA, submission. We and Ventana will generate data on the IVD, including the necessary analytical and clinical validation studies, with the goal of being in a position to submit a PMA and, assuming a successful outcome for the LEAP trial, seek approval of the PMA for the IHC hENT1 assay substantially simultaneously with the approval of an NDA for CO-101. In the European Union, the EMA is not currently involved in approving companion diagnostics and, instead, Ventana will apply for a CE mark designation in the European Union that will allow it to sell the diagnostic in the European Union.

Study CO-101-002: Establishing a hENT1 Cut-Off. Having developed the IHC assay with Ventana, we also needed to establish a "cut-off" for determining whether an individual patient is hENT1-high or hENT1-low. This cut-off must be robust such that the assay will provide consistent results when run and interpreted in different geographies by different labs and pathologists. Our goal is for a patient who presents with metastatic pancreatic cancer to undergo a metastasis biopsy and subsequent IHC assay that will be interpreted by a local pathologist, to determine whether a patient is hENT1-low and thus a good candidate for CO-101 therapy. In order to prospectively establish the hENT1-high/low cut-off, we commenced study CO-101-002. Pursuant to the protocol for this study, we collected tumor tissue samples from previously completed clinical studies of gemcitabine for the treatment of pancreatic cancer. Using the Ventana IHC assay, we assessed the hENT1 levels in each of the tissue samples and correlated the hENT1 expression with clinical outcomes. We then defined a cut-off level of hENT1 expression that is optimally associated with overall survival outcomes following gemcitabine therapy. According to the hypothesis, patients with tumor hENT1 expression levels below the cut-off will derive minimal benefit from gemcitabine and will constitute the prospectively defined hENT1-low population in the LEAP trial. Collection and analysis of the tissue samples is complete and we established the hENT1 cut-off in October 2011. Importantly, patients from LEAP will thus be prospectively classified as hENT1-high or -low before data from the ongoing LEAP trial are known. The primary efficacy analysis for LEAP is in hENT1-low patients, and their prospective classification prior to analyzing survival outcomes is important to ensure study integrity. Based on the published results of multiple studies assessing the correlation of hENT1 expression to survival outcomes in pancreatic cancer patients treated with gemcitabine, which found similar distributions of pancreatic cancer patients with low expressions of hENT1, as well as the prospective hENT1 classification of the first 250 patients enrolled in our ongoing pivotal study of CO-101, we believe that approximately one-half to two-thirds of pancreatic cancer patients are hENT1-low.

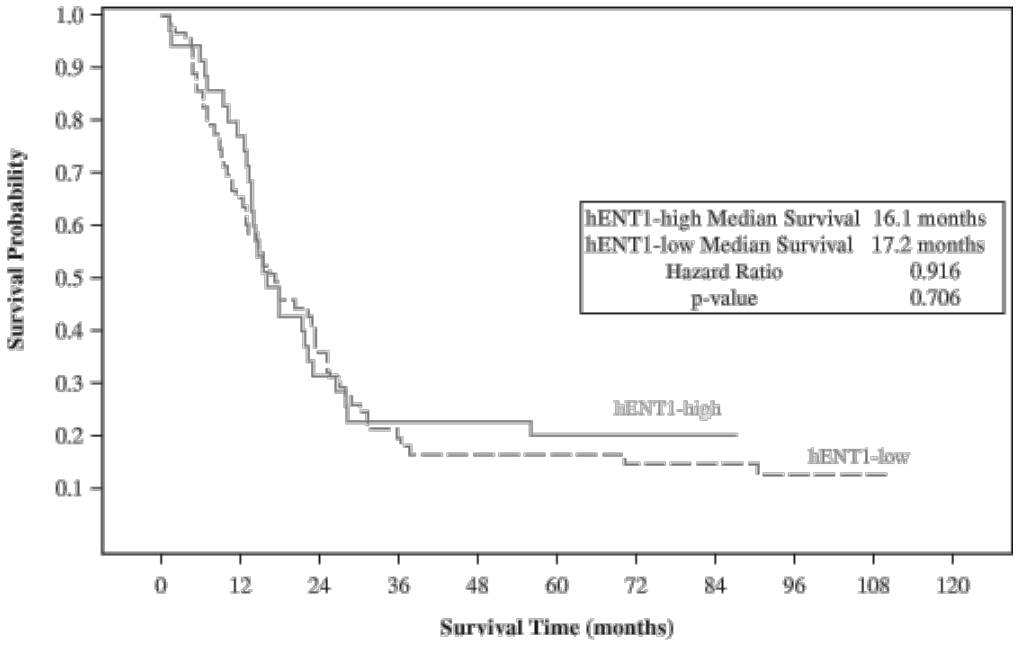
As part of study CO-101-002, we analyzed tissue samples from a large comparative study comparing adjuvant gemcitabine to adjuvant 5-FU in pancreatic cancer. These patient samples were from the same study evaluated by Farrell, et al., and published in Gastroenterology in 2009. In this analysis, using the Ventana hENT1 IHC assay, we were able to establish a rigorous algorithm of two qualitative measurements (intensity of staining and area stained) to stratify patients into hENT1-low and hENT1-high. Using this algorithm, the hENT1-high gemcitabine treated patient population had a median survival of approximately 24 months versus approximately 15 months for the hENT1-low gemcitabine treated population. We also evaluated 5-FU survival outcomes based on hENT1 status and detected no difference in survival related to hENT1. Using this algorithm, approximately two-thirds of patients in both the gemcitabine and 5-FU arms were hENT1-low.

The gemcitabine analysis had a p-value of 0.018 and a hazard ratio of 0.58. In clinical trials, the p-value is the probability of obtaining a test statistic at least as extreme as the one that was actually observed, assuming-as true-the hypothesis that a potential treatment has no effect. A p-value of 0.018 is considered statistically significant. The hazard ratio is a statistical measure of the relative risk of death for patients in different groups. A hazard ratio of 0.58 means that a hENT1-high patient treated with gemcitabine has a 42% lower chance of dying than a hENT1-low patient. The Kaplan-Meier curves for this study are shown in the figure below.

Kaplan-Meier Curves for 38 hENT1-high and 64 hENT1-low Pancreatic Cancer Patients After Receiving Adjuvant Gemcitabine

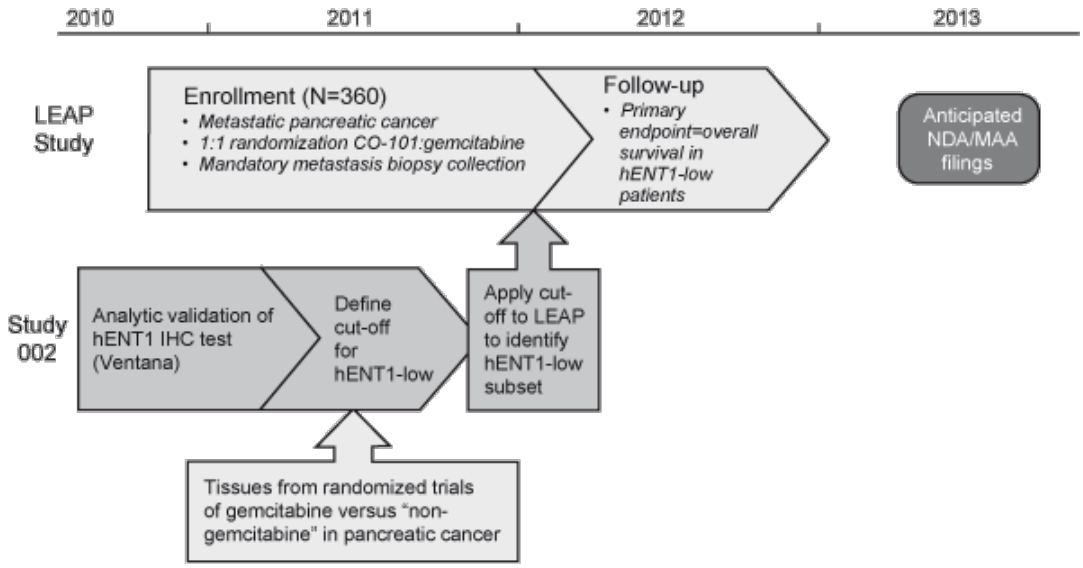


Kaplan-Meier Curves for 35 hENT1-high and 64 hENT1-low Pancreatic Cancer Patients After Receiving Adjuvant 5-FU



Based on this analysis, as well as that analysis of other tissue samples, we selected this algorithm as the basis for setting the hENT1 cut-off for the LEAP study. In addition, a 16-patient study of matched metastatic and primary tumor samples from the same patients demonstrated 100% correlation of hENT1 classification in the metastatic samples as in the primary samples using our selected algorithm. The hENT1-low population in this study was also approximately 66%. In January 2012, this percentage was prospectively confirmed when we announced that the Independent Data Monitoring Committee for the LEAP trial informed us that 65 percent of the first 250 patients enrolled in LEAP had been classified as hENT1-low. We remain blinded as to the hENT1 status of individual patients within the LEAP trial.

The following chart shows the LEAP study and companion diagnostic validation study design:



Study CO-101-003: a Phase II Study in Second-Line Pancreatic Cancer. We are also conducting a Phase II study to evaluate the efficacy of CO-101 as a second-line treatment for pancreatic cancer patients whose disease has progressed after first-line therapy and whose tumor tissue samples demonstrate a complete absence of hENT1 using an IHC diagnostic test. Study CO-101-003 is being conducted at up to 20 investigational centers in the United States. The first patient was enrolled in February 2011 and enrollment is expected to be completed in mid-2013.

Study CO-101-003 uses an open-label, single-arm, two-stage, Phase II design to evaluate CO-101 as second-line therapy in patients with measurable metastatic pancreatic cancer whose best response to gemcitabine as a first-line therapy, measured radiographically after treatment, was progressive disease; that is, patients who received no demonstrable benefit from gemcitabine therapy. Patients receive the same dosing regimen of CO-101 as in the LEAP trial. The primary endpoint for this study is disease control, which is defined as a complete response, partial response, or stable disease using response evaluation criteria in solid tumors, or RECIST, a set of published rules that define when a cancer patient responds, stabilizes, or progresses during treatments. After the first 18 patients have been assessed, the remaining 17 patients will be treated only if three or more patients in the initial 18-patient cohort have exhibited disease control. The study will close when a six-month follow-up has been completed for all patients. If meaningful numbers of patients experience extended stable disease or even partial responses on CO-101, we will view the study as successful in demonstrating CO-101's activity in second-line pancreatic cancer.

Other Potential Indications for CO-101: the hENT1 Hypothesis Applied to other Cancers . In addition to its use in pancreatic cancer, gemcitabine is approved, generally in combination with platinum chemotherapies, for use in NSCLC, ovarian and breast cancer, and we believe the hENT1 hypothesis could be applicable in each of these types of cancers. A small amount of preliminary data suggests the efficacy of gemcitabine in combination with cisplatin in NSCLC may relate to hENT1 expression. Consequently, we are considering clinical studies of CO-101 in other tumor types, initially NSCLC, and will seek to confirm a hENT1 cut-off using the Ventana IHC assay in these tumors. Testing of the IHC assay will be undertaken using lung tissue samples obtained from previously completed studies of gemcitabine in NSCLC, using a retrospective tissue collection protocol. The primary objective of the study will be to correlate the hENT1 expression with clinical outcomes in order to confirm the cut-off level of hENT1 that is optimally associated with treatment outcomes and survival in NSCLC patients treated with gemcitabine in combination with cisplatin. We plan to initiate a Phase I study of CO-101 in combination with cisplatin in advanced solid tumors in the third quarter of 2012.

Early Clinical Development of CO-101

During its initial development by Clavis Pharma, CO-101, identified by Clavis Pharma as CP-4126, was the subject of two clinical trials:

Study CP4126-201: an Abbreviated Phase II Study Conducted by Clavis Pharma. In June 2009, Clavis Pharma initiated a Phase II, open-label, multicenter European study evaluating CO-101 in patients with advanced pancreatic cancer. This study started as a single-arm study and included patients with locally advanced as well as metastatic disease, who had no prior chemotherapy for advanced disease. The patients were treated with CO-101 1250 mg/m ^{2} once per week for three out of every four weeks. The primary endpoint was change in a specific tumor marker, CA 19-9, and secondary endpoints were overall survival and overall response rate according to RECIST. Tumor hENT1 status was analyzed using an academically available assay only after patients were enrolled and treatment had begun. The protocol was amended in July 2009 to replace the single-arm treatment with a randomized treatment allocation to either CO-101 or gemcitabine after the first 10 patients had been enrolled in the study.

Upon obtaining the rights to CO-101, we and Clavis made the decision to stop this trial and begin the LEAP study, which, for the reasons set forth in detail below, we believe offers the potential for an accelerated pathway to approval. Due to the small number of patients in each treatment group of the Clavis Pharma trial, meaningful treatment comparisons between CO-101 and gemcitabine with respect to the primary endpoint of CA 19-9 response and overall survival could not be made. Twenty-one patients completed this study. Analysis of the data from this study was completed in December 2011 and shows the following: two patients in the CO-101 treatment group (N=15) had a partial response with a median duration of response of 115 days, driving an overall response rate of 13.3%, whereas no patients in the gemcitabine group (N=6) had a response. Five additional CO-101 patients achieved stable disease, some for a prolonged period, including one patient for 8 months. When analyzed in the subset of patients with metastatic disease and performance status of 0-1, a set of patient criteria similar to the ongoing LEAP study, the median overall survival time for CO-101 recipients was 7.5 months (N=14) versus 6.1 months for patients receiving gemcitabine (N=4). In this same subset, when analyzed by hENT1 status, the median survival time for hENT1-low patients was 9.3 months for CO-101 (N=3) and 3.6 months for gemcitabine (N=1). The activity of CO-101 appeared to be independent of hENT1 status, whereas the activity of gemcitabine appeared to be correlated with hENT1 expression.

All patients in the study experienced one or more treatment-emergent adverse events, or TEAEs. More than half of the CO-101 patients experienced nausea and/or vomiting, which were the most frequent TEAEs reported and occurred at higher frequencies than gemcitabine. There were 29 Grade 3 and five Grade 4 events in the CO-101 arm, the most significant level of TEAEs. The most frequent Grade 3 or 4 TEAE in both CO-101 patients and gemcitabine patients was neutropenia, a reduction in white blood cells. Neutropenia was also one of the events that led most often to dose reduction of CO-101, with the other being thrombocytopenia, or reduction in blood platelet cells, which was rarely assessed as Grade 3 or 4.

Phase I Trial: First in Man Study of CP-4126. The first-in-human study conducted by Clavis Pharma aimed to determine the maximum tolerated dose and the recommended dose for Phase II studies of CO-101. All 43 patients in the study finished treatment by January 2010. The most frequently reported toxicities were mild (Grade 1-2) nausea, vomiting, anorexia and fatigue. Myelosuppression, the impairment of bone marrow function, was also reported. Pharmacokinetic data suggested that CO-101 was present in plasma in a dose-proportional manner after IV administration. Gemcitabine can also be measured in plasma after CO-101 administration, and at the 1250mg/m ^{2} dose of CO-101, gemcitabine exposure exceeds that seen with conventional gemcitabine given at the standard dose of 1000mg/m ^{2}. Based on the dose limiting toxicities, the recommended Phase II dose of CO-101 was determined to be 1250 mg/m ^{2}, given as an IV infusion once per week for three out of every four weeks.

Regulatory Strategy

CO-101 LEAP Trial Design and Requirements for Regulatory Approval. In most cases, the FDA requires at least two adequate and well-controlled clinical trials to support marketing approval. In certain cases, evidence from a single clinical trial may be sufficient, and it is often the case in oncology where there is an unmet medical need. A single trial may be sufficient in cases where a multicenter study provides highly reliable and statistically strong evidence of an important clinical benefit, such as an effect on survival, and in which confirmation of the result in a second trial would be practically or ethically impossible.

We believe that if CO-101 meets the protocol specified endpoints of the LEAP study, this single Phase II clinical study should be sufficient for submission for marketing approval in the United States and the European Union. We have not sought an SPA for the LEAP study because we believe that the overall survival endpoint and other aspects of the study design are consistent with recent clinical guidelines for pancreatic cancer studies, as published in the Journal of Clinical Oncology in 2009. Nevertheless, in September 2010, in response to a briefing document and questions submitted to the FDA, we had a joint meeting with the oncology therapeutic and diagnostic device divisions of the FDA to review the clinical development plan for CO-101 and the development plan for its companion diagnostic. Based on this meeting and our adherence to established guidelines, we believe that this single clinical study could be used for registration if the results are positive. The adequacy of the safety and efficacy database will be a review issue, as with any submission. Similarly, following Protocol Assistance in the European Union, the Committee for Medicinal Products for Human Use, part of the EMA, indicated that a submission based on this single clinical study could be acceptable provided a meaningful survival benefit is demonstrated.

Applications for FDA approval to market a new drug should be based on adequate and well-controlled studies in order to distinguish the effect of the drug from other influences, such as a spontaneous change in the disease, or a biased observation. The reports on adequate and well-controlled studies provide the primary basis for determining whether there is substantial evidence to support the claims for effectiveness of a new drug. The key characteristics considered in determining whether a study is adequate and well-controlled are as follows:

(1) The protocol clearly defines objectives and methods of analysis.

(2) The study design provides a valid comparison with a control and quantitative assessment of drug effect.

(3) The method for selection of subjects assures that they have the disease being studied.

(4) The method of assigning patients to the treatment and control groups minimizes bias and is intended to assure the comparability of the groups.

(5) Adequate measures are taken to minimize bias on the part of the subjects, observers and analysts of the data.

(6) The methods of assessment of response are well-defined and reliable.

(7) The analysis of the results of the study is adequate to assess the effects of the drug.

We believe that the LEAP study protocol meets these requirements and that the study fulfills the criteria of an adequate and well-controlled study. The protocol clearly defines the objectives and patient population. The methods of analysis are subject to a detailed statistical analysis plan. The protocol includes an active treatment control, which is the standard of care, gemcitabine. Various types of control arms can be used, but in oncology an active control is most often used. The sample size for the study is predetermined and the study is powered to provide a quantitative assessment of drug effect and detect a difference between treatments. The selection of subjects follows best practice principles and incorporates the guidance provided in a recent consensus report for clinical trials in pancreatic cancer.

Patients are randomized to therapy with CO-101 or gemcitabine, stratified to ensure the comparability of the groups and precautions are taken to minimize potential bias. The primary efficacy variable is overall survival, which is an objective endpoint and the “gold standard” for measurement of efficacy for oncology clinical trials. Survival is considered the most reliable cancer endpoint and bias is not considered to be a factor in endpoint measurement.

CO-101 has an orphan drug designation in the United States and the European Union for the treatment of pancreatic cancer. If a product that has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the U.S. and ten years in the European Union. Orphan drug designation does not prevent competitors from developing or marketing different drugs for an indication. Orphan drug designation must be requested before submitting an NDA or MAA. After orphan drug designation is granted, the identity of the therapeutic agent and its potential orphan use are publicly disclosed. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process for a drug by the applicable regulatory authority.

The regulations for accelerated approval for new drugs for serious or life threatening illnesses often referred to as subpart H, do not apply to the LEAP study. Although CO-101 is being developed for a serious and life threatening disease, this guidance applies to approvals based on a surrogate endpoint or clinical endpoint other than survival. Since the endpoint in the LEAP study is survival, the NDA would be subject to a regular approval procedure. CO-101 requires the concomitant availability of an in vitro diagnostic device to identify the relevant patient population. This diagnostic needs to be available in parallel with the drug product and therefore the development plan for CO-101 allows for the diagnostic to be developed and validated in a time frame that will allow for regulatory approval at the same time that CO-101 would be approved. We are working with Ventana to develop the data necessary for a PMA submission with the FDA. Assuming a successful outcome of our LEAP study, we expect that Ventana will submit a PMA for the hENT1 IHC assay in parallel with our submission of an NDA for CO-101 such that approval would be expected at the same time for both products.

CO-1686—an Oral EGFR Mutant-Selective Inhibitor

Overview

CO-1686 is a new chemical entity we in-licensed pursuant to an agreement effective May 2010 from Avila Therapeutics, Inc., a privately held biotechnology company in Waltham, Massachusetts. It is a novel, orally available, small molecule covalent inhibitor of the cancer-causing mutant forms of EGFR for the treatment of NSCLC. Because CO-1686 targets both the initial activating EGFR mutations as well as the primary resistance mutation, T790M, it has the potential to treat both first- and second-line NSCLC patients with EGFR mutations. According to a study published in Clinical Cancer Research in 2008, such initiating activating mutations occur in approximately 10% to 15% of NSCLC cases in Caucasian patients and approximately 30% to 35% of NSCLC cases in East Asian patients. Based on multiple published reports, including a study in Nature Reviews Cancer in 2007, following treatment with Tarceva® (erlotinib) or Iressa® (gefitinib), approximately half of these patients develop the T790M mutation. In January 2012, the FDA accepted our investigational new drug application to begin clinical investigation of CO-1686. Initial Phase I/II studies of CO-1686 are expected to commence in the U.S. and Europe in the second quarter of 2012 and in Asia during the third quarter of 2012.

Market Overview: Resistance to EGFR Tyrosine Kinase Inhibitors, or TKIs, Represents an Unmet Medical Need

Lung Cancer and EGFR TKIs. According to the American Cancer Society, there were an estimated 223,000 new cases of lung cancer in the United States in 2010, making it the most common type of cancer. In addition, according to Cancer Research UK, there are an estimated 288,000 new cases of lung cancer in the European Union each year and, according to a white paper entitled "Cancer White Paper—Incidence/Death/Prognosis—2004" (Shinoharashinsha Inc.), there are an estimated 85,000 new cases in Japan each year. Lung cancer typically presents relatively late in its clinical course, when locally directed therapy (surgery and radiation) is not curative. The treatment of locally advanced and metastatic lung cancer is a significant unmet medical need.

Lung cancer is typically divided into two groups based upon the histologic appearance of the tumor cells—small-cell and non small-cell lung cancer, each of which is treated with distinct chemotherapeutic approaches. According to the American Cancer Society, NSCLC accounts for approximately 85% of lung cancer cases, and can be subdivided into further histologic subsets—adenocarcinoma, bronchioalveolar, squamous cell, anaplastic and large cell being the most common—although until recently treatment was similar for all of these subsets. The standard of care for treatment of advanced or metastatic NSCLC has historically been a cytotoxic chemotherapy doublet of platinum plus paclitaxel. In the last few years, specifically for non-squamous cell, a subset of NSCLC patients, Avastin® (bevacizumab) has been shown to prolong survival when added to the doublet, and Alimta ® (pemetrexed) has replaced paclitaxel on the basis of improved tolerability and ease of administration. Despite these additions, patients with locally advanced or metastatic NSCLC have five-year survival rates of just 24% and 4%, respectively, according to the Survival Epidemiology and End Results program of the National Cancer Institute.

Approximately 10 years ago, orally active small molecule inhibitors of the tyrosine kinase activity of EGFR were introduced into the treatment of lung cancer. The growth-promoting EGFR was known to be frequently expressed on lung cancer cells, often at high levels, and preclinical work had suggested that EGFR TKIs, such as gefitinib and erlotinib, could provide effective cancer therapy in certain patient subsets. Clinical trials were conducted in humans with NSCLC and the drugs were approved by the FDA in 2003 (Iressa® (gefitinib)) and 2004 (Tarceva® (erlotinib)) for patients who had failed to respond to conventional chemotherapy. It was noted in a study published in Nature Reviews Cancer in 2010 that a small subset of patients experienced profound tumor responses to TKI therapy.

In 2004, it was discovered that the subset of NSCLC patients who experienced dramatic clinical responses to the EGFR TKIs had activating mutations in the EGFR gene in their lung cancer tissue, known as an L858R mutation, rendering the EGFR protein hyperactive. It became clear that the EGFR TKIs potently inhibited the mutant EGFR proteins, switching off their activity and causing dramatic tumor shrinkage in patients. This is an example of "oncogene addiction", whereby a single gene mutation (EGFR in this case) is absolutely necessary for the proliferation and/or survival of a tumor cell. A corollary of this situation is that inhibition of that single gene product (in this case with TKIs) is therapeutic and drives tumor shrinkage. It was subsequently shown in a study conducted by Jeffrey A. Engelman, et al. published in Clinical Cancer Research in 2008 that EGFR mutations generate tumors with adenocarcinoma histology, and are found in approximately 10% to 15% of Caucasian NSCLC patients and 30 to 35% of East Asian NSCLC patients.

The original approvals of the TKIs made no reference to patient selection, but these new data have suggested that the majority of their therapeutic benefit can be attributed to the subset of patients with activating EGFR mutations. Recent clinical trials have shown that for patients with activating EGFR mutations, treatment with TKIs is superior to standard cytotoxic chemotherapy as it has resulted in superior progression free survival and improved quality of life. Consequently, many cancer therapy guidelines (National Comprehensive Cancer Network and American Society for Clinical Oncology) suggest that patients with adenocarcinoma histology NSCLC should undergo genetic testing for EGFR mutations and TKIs should be used in those patients with identified activating mutations. Molecular testing of NSCLC tissues for EGFR mutations has become standard across many countries, although no specific diagnostic test is included in the regulatory labels for any of the approved TKIs to date.

Resistance to EGFR TKIs. Despite the success of TKIs in patients with mutant EGFR-related NSCLC, most patients' disease will progress, typically after approximately one year of therapy. Molecular studies have shown that approximately 50% of the resistant tumors carry a second, acquired resistance mutation in the EGFR gene. This resistance mutation is a specific change in the type of amino acid located at position 790 in the EGFR protein, called a "T790M" mutation. As a consequence of this switch the three-dimensional structure of the TKI binding site changes and thus the EGFR becomes resistant to TKI therapy. This T790M mutation is also called the "gatekeeper" mutation because of its strategically important position in the EGFR protein.

An early approach to therapy for this important resistance mutation was to develop covalent inhibitors, drugs that bind irreversibly through a covalent bond to their receptor target, and permanently inactivate it. There is a specific location on the EGFR protein, a cysteine residue, that is close to the protein's active site, and is where most covalent drugs bind to in order to achieve their inhibitory effect. We are aware of two product candidates currently in clinical development that bind to this cysteine residue in EGFR, which are referred to as "second generation" TKIs. Both drugs have been tested in patients with the T790M mutation in their EGFR, but no responses have been reported to date. We believe the likely explanation for this effect is that these drugs are extremely potent inhibitors of the normal form of the EGFR, and cause very substantial toxicity in the skin (rash) and intestine (diarrhea) which limits dosing significantly. Patients appear to be unable to tolerate the dose of drug needed to inhibit the T790M mutant EGFR in a lung tumor. Consequently, at present, patients who develop TKI resistance receive standard cytotoxic chemotherapy that carries toxicity and only modest palliative efficacy, and all patients will ultimately succumb to their disease. Thus, patients with mutant EGFR-related NSCLC who also carry the T790M mutation represent a defined subset of patients with a clear unmet medical need.

Opportunity for Clovis

We partnered with Avila to discover and develop an orally active, small molecule covalent inhibitor of the mutant forms of EGFR that does not bind to unmutated or normal EGFR. We identified CO-1686 as a potential product candidate because it has three important potential advantages:

- potential to effectively treat patients with T790M mutant EGFR NSCLC—a large and growing group of patients, which have been identified with greater frequency due to recently approved guidelines, who today have no effective therapy;
- potential to effectively treat patients with initial activating mutations in the EGFR who receive "first-generation" TKIs, but develop resistance due to the acquired T790M mutation; CO-1686 would be expected to prevent resistance through this mechanism and may thus cause responses of greater duration than seen with first generation TKIs and extend progression-free survival; and
- it would not be expected to inhibit normal EGFR in skin or intestine, and thus would be less likely to cause skin rash and diarrhea, which are dose limiting with all other EGFR inhibitors.

Design of CO-1686—a Targeted Covalent Drug

Most human diseases are rooted in the improper activity of certain proteins. Traditional small molecule drugs, while able to inhibit disease-causing proteins, are generally only able to form transient binding interactions with the disease targets, and thus considered reversible. A covalent drug, however, forms a strong and durable bond with its protein target, known as a covalent bond. A targeted covalent drug is designed to form its covalent bond in a highly directed and controlled manner with a specific site on the disease target. This directed bond formation is key to achieving a distinct selectivity profile that is difficult to achieve with traditional reversible small molecules.

Covalent drugs have been developed by the pharmaceutical industry for decades, with several successfully commercialized, including Nexium ®, Plavix® and penicillins. However, these drugs were not intentionally designed to be covalent drugs. Avila has developed a proprietary platform called Avilomics™ to purposefully and systematically design and develop targeted covalent inhibitors. CO-1686 was designed using this platform.

There are a number of drugs both on the market and being developed that inhibit various kinases, including EGFR. Because kinases are structurally similar to each other, it is difficult to design small molecules that selectively inhibit a single kinase that do not also inhibit other kinases to some degree. Most kinase inhibitors are only modestly selective and inhibit a variety of kinases; these are typically referred to as "multi-kinase inhibitors."

However, because of the design of its bond-forming capability, a targeted covalent drug is potent against the disease target of interest, including EGFR, and due to its selectiveness, it is not potent against other targets, even related targets. This is important to avoid undesired "off-target" side effects which can occur with reversible small molecules, such as multi-kinase inhibitors which are not highly selective.

A targeted covalent approach was employed by Avila in order to design a drug that could potently inhibit the mutant forms of EGFR, while sparing normal EGFR.

Avila designed CO-1686 by identifying a site on the EGFR protein where a covalent bond could be formed and used its proprietary drug design techniques to model chemical structures that could selectively form a bond with this site. These molecules were then synthesized and tested in assays to verify their ability to form targeted covalent bonds and to potently inhibit the mutant forms of EGFR and also to demonstrate that covalent bonds were not formed indiscriminately with other targets.

Preclinical Development

CO-1686 has demonstrated up to 200-fold greater binding selectivity for EGFR activating mutations and the T790M resistance mutation relative to the normal receptor when evaluated in vitro. Binding to normal EGFR can cause significant side effects, such as rash and diarrhea, which have been observed upon treatment with first and second-generation EGFR inhibitors. Furthermore, experiments have been conducted in which human tumor tissue or cells have been implanted in mice or rats. These experiments, known as xenograft models, have demonstrated that CO-1686 can lead to tumor regression in two relevant models of EGFR-driven lung cancer tumors. The H1975 model employs tumors that contain both the L858R activating EGFR mutation and the T790M resistance mutation. This model represents EGFR-driven NSCLC that is resistant to Tarceva ® (erlotinib). Use of CO-1686 in this model demonstrates a dose response with drug activity at doses of 30mg/kg and greater activity at doses of 100mg/kg. In addition, because CO-1686 is designed to spare the normal EGFR receptor, the drug was well tolerated at all dose levels with no apparent body weight loss in the mice, which is a surrogate measure for intestinal toxicity.

In January 2012, the FDA accepted our investigational new drug application to begin clinical investigation of CO-1686. Initial Phase I/II studies of CO-1686 are expected to commence in the U.S. and Europe in the second quarter of 2012 and in Asia during the third quarter of 2012.

Clinical Development

We have designed an accelerated clinical development program for CO-1686, and if successful, have a goal of filing an NDA for an initial indication within approximately four years of filing our IND. We intend to pursue the development of CO-1686 as both a second-line treatment for EGFR-mutated NSCLC patients who become resistant to TKIs due to the emergence of the T790M mutation and, potentially, as a first-line treatment for EGFR-mutated NSCLC. We expect to initiate a Phase I/II trial of CO-1686 in the second quarter of 2012. Data from this trial will be used to determine the tolerability and pharmacokinetics of CO-1686, as well as provide evidence of efficacy in selected NSCLC patients with the T790M mutation. We anticipate receiving preliminary data from this trial in the second half of 2013. Once we complete the dose ranging portion of the study, we plan to enroll an expanded cohort of NSCLC patients with the T790M mutation to test the efficacy of CO-1686 in the selected patient subset. If this study is successful, it will be followed by a pivotal trial in T790M mutant positive NSCLC patients as a second-line treatment following TKI failure. At the same time, pending data from the Phase I/II study, we may initiate a study comparing CO-1686 to Tarceva® (erlotinib) in confirmed EGFR-mutant NSCLC patients.

In addition to the drug development program, we have commenced a collaboration for the development of a companion diagnostic to enable identification of patients with the T790M mutation. We believe such a patient selection tool would enable a focused clinical development plan, thereby enhancing response rate and optimizing the benefit-to-risk ratio for CO-1686. To achieve this goal, we have partnered with Roche to develop a molecular diagnostic test for EGFR mutations including T790M. The eventual goal of the collaboration is to commence a pivotal trial of CO-1686 in patients selected for the T790M mutation using a PCR-based tool. The diagnostic test will be developed in parallel with the clinical development of CO-1686, with the goal of filing a PMA with the FDA in a time frame that would allow for regulatory approval of the companion diagnostic at substantially the same time that CO-1686 would be approved.

Rucaparib—a PARP Inhibitor

Overview

Rucaparib, also known as CO-338, is a new chemical entity we in-licensed from Pfizer Inc. in June 2011. Formerly known as PF-01367338 and AG-014699, rucaparib is a novel, orally available, small molecule poly ADP-ribose polymerase, known as PARP, inhibitor that we intend to develop as both monotherapy and as a therapy in combination with chemotherapeutic agents for the treatment of patients with cancers predisposed to PARP inhibitor sensitivity. Such cancers include serous ovarian cancer and selected patients with breast cancer. Pursuant to our license agreement with Pfizer, we possess global development and commercialization rights to rucaparib.

Rucaparib is currently in a Phase I clinical trial to determine the maximum tolerated dose of oral rucaparib that can be combined with IV platinum chemotherapy in the treatment of solid tumors. This program is supplemented by two ongoing investigator-initiated trials: a Phase I/II monotherapy study in hereditary, or germ-line, BRCA mutant breast and ovarian cancer and a Phase II randomized study of cisplatin, with or without rucaparib, in the adjuvant treatment of high-risk germ-line BRCA mutant and triple-negative breast cancer, a particularly difficult to treat form of breast cancer. In the fourth quarter of 2011, we initiated a Phase I/II monotherapy study of the oral formulation to determine an appropriate dose and schedule for long term administration, and to then assess preliminary efficacy in breast and ovarian cancers, including in patients with germline mutations in BRCA genes.

DNA Repair and PARP

Cells in the human body are under constant attack from agents that can cause damage to DNA, including sunlight and other forms of radiation, as well as DNA-binding chemicals that can cause changes in the composition of DNA. Since DNA is the vehicle by which fundamental information is passed on when a cell divides, it is critical to the integrity of cells and human health that DNA damage can be repaired. Cells have evolved multiple mechanisms to enable such DNA repair, and these mechanisms are complementary to each other, each driving repair of specific types of DNA damage. If a cell's DNA damage repair system is overwhelmed, then the cell will undergo a form of suicide called apoptosis that appears to operate as a fail-safe system to limit the ability of a mutated cell to proliferate and potentially form a cancer. A fundamental principle of cancer therapy is to damage cells profoundly with radiation or DNA-binding drugs, for example alkylating agents or platinums, and induce apoptosis in those cells, thus killing the cancer cells. DNA repair mechanisms may reduce the activity of these anti-cancer therapies but, conversely, inhibition of DNA repair processes may enhance the effects of DNA-damaging anti-cancer therapy.

Poly-ADP ribose (PAR) is a part of the early warning system for DNA damage, and is synthesized by PARP enzymes on regions of damaged DNA, where it signals to the cell that DNA repair needs to take place. In the absence of PARP, as is seen in gene-knockout mice, cells are unusually sensitive to DNA damage when exposed to radiation or DNA-alkylating agents. There are two major forms of PARP that signal DNA damage in this way, PARP-1 and PARP-2. Knockout of either PARP gene leads to enhanced DNA damage in both instances although the mice may survive. However, the double knockout in which both the PARP-1 and PARP-2 genes are deleted is fatal to the mice at an embryonic stage. We believe that a drug that inhibits both PARP-1 and PARP-2 may have enhanced activity in preventing DNA repair.

As small molecule inhibitors of PARP became available, they were tested for their ability to inhibit DNA damage repair and potentiate the effects of radiation or cytotoxic chemotherapy, and were shown to be potent enhancers of these anti-cancer therapies in preclinical studies. Subsequently, PARP inhibitors have been explored in clinical trials as "chemopotentiators", often in combination with drugs that add alkyl groups to DNA, such as temozolamide. Results to date have demonstrated anti-cancer activity, but have clearly demonstrated the need for patient selection in order to show compelling data.

Synthetic Lethality

A large advance in the field came when it was recognized that germ-line mutations in the BRCA genes (BRCA1 and BRCA2, two tumor suppressor genes) were associated both with high rates of breast and ovarian cancer in female mutant gene carriers, and also impaired the ability of cells to repair DNA damage. BRCA gene products were shown to be key mediators of DNA repair. The notion was advanced that treatment of BRCA-defective cells with PARP inhibitors could lead to a disabling blow against a tumor cell's ability to repair DNA and could induce apoptosis. This phenomenon was termed "synthetic lethality" and was demonstrated in a study conducted by H. Farmer, et al., published in Nature in 2005 to be true in vitro, and then, in a study conducted by Peter C. Fong, M.D. et al., published in the New England Journal of Medicine in 2009, it was shown to be valid in humans, as evidenced by women with advanced breast and ovarian cancer and germ-line BRCA mutations experiencing objective tumor responses when treated with monotherapy PARP inhibitors.

Germ-line BRCA mutations are a minority subset of all breast and ovarian cancers, and the hypothesis was explored that some tumors might have defective BRCA function for reasons other than germ-line gene mutation. This notion has been called "BRCA-ness". Subsequent work has shown that BRCA-ness exists, and that cancer patients with normal germ-line BRCA genes can respond to monotherapy with PARP inhibitors. Work is underway to identify a molecular signature for "BRCA-ness" that could enable patient selection for therapy. As a complement to the work to identify a BRCA-ness signature, clinical criteria have been developed to identify patients likely to respond to PARP inhibitors. If the notion of synthetic lethality is accepted, then PARP inhibitors should work well in patients with pre-existing defective DNA repair in their tumors. Defective DNA repair in a tumor would likely mean that the tumor is responsive to DNA-damaging chemotherapy, since the therapeutic DNA damage that triggers apoptosis cannot be effectively repaired by the tumor cell. Platinum chemotherapy drugs are a good example of one such DNA-damaging agent. To examine the hypothesis that platinum-sensitive tumors will respond to PARP inhibition, ovarian cancer patients have recently been studied, since ovarian cancer typically responds well to initial platinum-based chemotherapy, although relapses are expected after several months. Recent data from a study abstract published in the Journal of Clinical Oncology in 2011 demonstrated that in women with advanced ovarian cancer who have responded twice to platinum chemotherapy, maintenance therapy with an oral PARP inhibitor approximately doubled the time until disease progression versus a placebo-treated arm. This study was not conducted in all ovarian cancer subtypes, but specifically in high grade serous ovarian cancer. According to the National Cancer Institute, there are approximately 22,000 new cases of ovarian cancer each year. According to Cancer: Principles and Practice of Oncology (7th Edition, 2005), high grade serous ovarian cancer accounts for approximately 90% of ovarian cancers. According to an article published in Nature Reviews Clinical Oncology in 2010, BRCA mutation, or BRCA-ness, is believed to be present in at least 50% of high grade serous ovarian cancer tumors.

PARP Inhibitor Development Strategy

Based upon the basic science observations and clinical data described above, we will consider at least three ways to develop rucaparib for the treatment of solid tumors:

- monotherapy in germ-line BRCA patients (mostly breast and ovarian cancer although a few patients develop tumors in pancreas and prostate);
- monotherapy (induction and/or maintenance therapy) in patients with high BRCA-ness tumors; and
- combination therapy with cytotoxic chemotherapy or radiation or targeted therapy in other tumors.

These approaches will require, in many cases, a patient selection strategy utilizing either a molecular diagnostic or a clinical filter. Consistent with our strategy with other projects, we will consider partnering with a molecular diagnostic company to develop a companion diagnostic where it is needed. Some indications, as noted above, may be adequately explored using clinical selection criteria and obviate the need for a companion diagnostic.

Opportunity for Clovis

Within the universe of PARP inhibitors, we were particularly attracted to the profile of rucaparib from a variety of perspectives:

- it is a very potent inhibitor of PARP-1 and PARP-2 proteins;
- the oral formulation offers good bioavailability and low inter-individual pharmacokinetic variability;
- it can be used as monotherapy in germ-line BRCA patients and has shown activity in this setting (with the IV formulation);
- it can be used in combination with cytotoxic chemotherapy and can be safely given at doses shown to be highly PARP inhibitory, as suggested by the trial results described below; and
- it can likely be used as oral maintenance therapy after cytotoxic chemotherapy.

Clinical Development of rucaparib

The IV formulation of rucaparib has been studied in two Phase I clinical trials and one Phase II clinical trial. The first Phase I clinical trial was designed to identify a dose of rucaparib that was both pharmaceutically active and well tolerated by patients and to identify the dose of temozolomide, or TMZ, a chemotherapy, that could be combined with rucaparib in a safe and well-tolerated manner. After appropriate dose-escalation, the study concluded that the recommended treatment dose of rucaparib was 12 mg/m^2 each day with TMZ 200 mg/m^2 each day.

A subsequent Phase II study evaluated the combination of rucaparib and TMZ in patients with metastatic melanoma. Forty-six patients were treated at the dose level of 12 mg/m^2 each day for three cycles and TMZ 200 mg/m^2 every 21 days. Seventeen percent of patients achieved a partial response, an additional 17% had stable disease of greater than or equal to 24 weeks, the median progression free survival was 3.5 months and median overall survival was 9.9 months. The most common adverse events for the rucaparib and temozolomide combination were gastrointestinal, including nausea and vomiting.

The second Phase I clinical trial is a tolerability and pharmacokinetic study of escalating doses of oral rucaparib (given for 2 of 3 weeks) administered in combination with carboplatin (given once every 3 weeks) in patients with solid tumors. The study previously evaluated the intravenous form of rucaparib (given for 3 days every 3 weeks) administered in combination with four different chemotherapy regimens (carboplatin, carboplatin/paclitaxel, pemetrexed/cisplatin and epirubicin/cyclophosphamide). The latter 3 chemotherapy combinations have since been discontinued. A total of 60 patients have been treated to date, including 6 patients in 2 dose cohorts on the extended treatment schedule (14 days) with oral rucaparib. No maximum tolerated dose in extended treatment has yet been reached and dose escalation is ongoing. In a preliminary assessment of efficacy, three patients had a partial response (30% decrease in the longest diameter of the target lesions), including one in a breast cancer patient with a BRCA defect, one in a breast cancer patient with no observable BRCA defect, and one in an ovarian cancer patient with a BRCA defect.

An oral, continuous daily dosing schedule has not been robustly established for rucaparib monotherapy. Therefore, in the fourth quarter of 2011 we initiated a Phase I monotherapy study of the oral formulation to determine the optimal dose and schedule. Once the appropriate dose and schedule has been determined, we intend to expand this study to enroll selected ovarian and breast cancer patients to assess the efficacy of rucaparib in these patient populations.

Our rucaparib clinical development plan is supplemented by two investigator-sponsored trials of rucaparib. One is a Phase I/II monotherapy trial in the treatment of germline BRCA mutation breast and ovarian cancer; the second is a Phase II randomized trial in the adjuvant treatment of patients with high risk germline BRCA-defective breast cancer and triple-negative breast cancer. In both of these studies, we have transitioned from the IV formulation to the oral dosage form for monotherapy, although the latter trial continues with IV formulation of rucaparib during the platinum-combination dosing period.

Upon analysis of the Phase I/II trial results, we may pursue future development of rucaparib as monotherapy and/or in combination with chemotherapy, most likely in serous ovarian and breast cancer indications. Other potential indications we may consider include NSCLC, endometrial cancer, and chronic lymphocytic leukemia. We may also study the inhibition of PARP in the maintenance setting after cytotoxic chemotherapy, which seems to be effective in the setting of certain cancers that are sensitive to platinum chemotherapy.

Competition

The commercialization of new drugs is competitive and we will face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Our competitors may develop or market products or other novel technologies that are more effective, safer or less costly than any that have been or will be commercialized by us, or may obtain regulatory approval for their products more rapidly than we may obtain approval for ours.

The acquisition or licensing of pharmaceutical products is also very competitive, and a number of more established companies, which have acknowledged strategies to license or acquire products, may have competitive advantages as may other emerging companies taking similar or different approaches to product acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines. These established companies may have a competitive advantage over us due to their size, cash flows and institutional experience.

Many of our competitors will have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

CO-101 Competition

There are currently two agents approved for the treatment of metastatic pancreatic cancer: Gemzar ®/gemcitabine marketed by Eli Lilly, Teva Pharmaceutical Industries, APP Pharmaceuticals, Hospira, Inc. and Sandoz Inc. and Tarceva® (erlotinib) marketed by Genentech and Astellas Pharma in the US and Roche Pharmaceuticals outside of the US. Gemcitabine represents the current standard of care across all lines of pancreatic cancer therapy, either as monotherapy or as part of combination regimens. In addition, although not an approved therapy, the National Comprehensive Cancer Network includes FOLFIRINOX (5FU/leucovorin plus oxaliplatin and irinotecan) in its recommended first-line treatment options for good performance status patients with metastatic pancreatic cancer.

There are a number of companies with active clinical trials ongoing in pancreatic cancer. Companies in late stage pancreatic cancer clinical trials include AB Science SA, Amgen Inc., Astellas Pharma, BioSante Pharmaceuticals, Inc., Celgene Corporation, Immunomedics, Inc., Lorus Therapeutics, Merrimack Pharmaceuticals, Inc., NewLink Genetics Corporation, and Threshold Pharmaceuticals, Inc. The majority of these companies have programs under development in combination with gemcitabine. We are not aware of any competitors with programs targeting low hENT1 expression in pancreatic cancer.

CO-1686 Competition

Tarceva® and Iressa® are two of the currently approved drugs that are used to treat EGFR mutant NSCLC. In addition, we are aware of two products in development targeting cancer-causing mutant forms of the epidermal growth factor receptor, or EGFR, for the treatment of NSCLC patients. These products include Boehringer Ingelheim's BIBW-2992 (afatinib), currently in Phase III trials, and Pfizer's PF-299804, currently in Phase II. We believe CO-1686 potentially offers several important advantages over the second generation EGFR inhibitors, including superior efficacy due to activity against the T790M resistance mutation and higher selectivity for the T790M mutation with relative sparing of normal EGFR, therefore avoiding the significant skin rash and gastro-intestinal toxicities associated with other first and second generation inhibitors, including Tarceva and Iressa. We also believe that other pharmaceutical companies may be seeking to develop EGFR mutant selective inhibitors that may enter clinical development on a similar time frame to CO-1686.

Rucaparib Competition

We believe the products in development targeting the PARP pathway consist of Abbott's ABT-888 (velaparib) currently in Phase II clinical trials, Merck's MK-4827 currently in Phase I trial, Eisai's E-7016 currently in Phase I trials, Cephalon's CEP-9722 currently in Phase I trials, and Biomarin's BMN-673 currently in Phase I trials.

License Agreements and Agreements for the Development of Companion Diagnostics

Clavis Pharma ASA

In November 2009, we entered into a license agreement with Clavis to obtain the exclusive rights to develop and commercialize CO-101 in North America, Central America, South America and Europe. The exclusive rights are exclusive even as to Clavis and include the right to grant sublicenses. Under the terms of the license agreement, we made an up-front payment to Clavis of $15.0 million, which was comprised of $13.1 million for development costs incurred prior to the execution of the agreement, and recognized by us as acquired in-process research and development, and $1.9 million for the prepayment of preclinical activities to be performed by Clavis. In November 2010, the license agreement was amended to expand the license territory to include exclusive rights in Asia and other international markets, in consideration for our making a payment of $10.0 million, which again we recognized as acquired in-process research and development. As part of the amended license, Clavis agreed to reimburse us for up to $3.0 million of costs incurred by us for CO-101 development activities. Under the amended license agreement, we are obligated to use commercially reasonable efforts to develop and commercialize CO-101, and with the exception of the specific amounts to be reimbursed by Clavis, we are responsible for all remaining development and commercialization costs for CO-101. When and if commercial sales of CO-101 begin, we will pay Clavis tiered royalties at percentage rates ranging from the mid-teens to the low twenties based on the volume of annual net sales achieved, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize CO-101 and royalty reductions in the event of generic competition, each on a country by country basis. We are required to make regulatory milestone payments to Clavis of up to $115.0 million if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are obligated to make sales milestone payments to Clavis if specified annual sales targets for CO-101 are met, the majority of which relate to annual sales targets of $500.0 million and above, which, in the aggregate, could amount to total milestone payments of $445.0 million.

Under the license agreement, for a limited period of time related to the timing of the filing of the first MAA for CO-101 in Europe, Clavis may elect to co-develop and co-promote CO-101 in Europe. If Clavis were to make this election, it would be required to reimburse us for either 35% or 40% of all development costs incurred by us up to the date of such election, depending on the timing of such election relative to the disclosure to Clavis of top line data from its first completed Phase II or Phase III clinical trial, and thereafter, Clavis would be required to pay us 25% of all ongoing development costs for CO-101. In addition, milestone payments described above would be reduced and, instead of receiving royalties on net sales in Europe, Clavis would share equally in the pretax profits or losses resulting from commercialization activities in Europe.

The license agreement will remain in effect until we or our sublicensees are no longer selling CO-101 in any country in our global licensed territory, unless we elect to terminate the license earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Clavis can terminate the agreement, resulting in a loss of our rights to CO-101 and an obligation to assign or license to Clavis any intellectual property rights or other rights we may have in CO-101, including our regulatory filings, regulatory approvals, patents and trademarks for CO-101.

Avila Therapeutics, Inc.

In May 2010, we entered into an exclusive worldwide license agreement with Avila to discover, develop and commercialize a pre-clinical covalent inhibitor of mutant forms of the EGFR gene discovered by Avila and selected by us. As a result of the collaboration contemplated by the agreement, CO-1686 was identified as the lead inhibitor candidate which we are proceeding to develop under the terms of the license agreement. Under the agreement, we are required to use commercially reasonable efforts to develop and commercialize CO-1686, and we are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize CO-1686. We made an up-front payment of $2.0 million to Avila upon execution of the license agreement, which we recognized as an acquired in-process research and development expense. When and if commercial sales of CO-1686 commence, we will pay Avila tiered royalties at percentage rates ranging from mid-single digits to low-teens based on annual net sales achieved. Avila has the option to increase royalty rates on annual net sales in the United States and the European Union by electing to reimburse us for a share of our development expenses for CO-1686. This option must be exercised within a limited period of time of Avila's being notified by us of our intent to pursue regulatory approval of CO-1686 in the United States or the European Union as a first-line treatment. Under the agreement, we are required to make regulatory milestone payments to Avila of up to $119.0 million if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are obligated to make sales milestone payments to Avila if specified annual sales targets for CO-1686 are met, the majority of which relate to annual sales targets of $500.0 million and above, which, in the aggregate, could amount to total milestone payments of $120.0 million. In January 2012, the U.S. Food and Drug Administration accepted our investigational new drug application to begin clinical investigation of CO-1686, which triggered the first development milestone payment to Avila of $4.0 million.

We have full sublicensing rights under the license agreement with Avila, subject to our sharing equally with Avila any up-front payments from any sub-licensing arrangements relating to Japan, or Japan and any one or more of China, South Korea and Taiwan, which we refer to herein as an Asian Partnership, and subject to our paying Avila royalties on sales in Asia equal to the greater of the royalty rates contained in our license agreement with Avila or 50% of the royalties we receive from our Asian Partnership.

The license agreement with Avila will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to Avila, determined on a product-by-product and country-by-country basis, unless we elect to terminate the license agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Avila can terminate the agreement, resulting in a loss of our rights to CO-1686 and an obligation to assign or license to Avila any intellectual property rights or other rights we may have in CO-1686, including our regulatory filings, regulatory approvals, patents and trademarks for CO-1686.

On January 26, 2012, Avila announced that it had entered into a definitive agreement with Celgene Corporation pursuant to which, subject to regulatory approval and other customary closing conditions, Celgene would acquire Avila, including Avila's intellectual property underlying CO-1686 and the right to receive the future compensation due under the license agreement. The acquisition was completed on March 8, 2012.

Pfizer Inc.

In June 2011, we entered into a license agreement with Pfizer, to obtain the exclusive global rights to develop and commercialize rucaparib. The exclusive rights are exclusive even as to Pfizer and include the right to grant sublicenses. Under the terms of the license agreement, we made an up-front payment by issuing to Pfizer $7.0 million principal amount of a 5% convertible promissory note due 2012. This promissory note was converted into shares of our common stock in connection with our initial public offering completed in the fourth quarter of 2011. Under the license agreement, we will assume responsibility for an ongoing Phase I dose ranging clinical trial previously conducted by Pfizer examining the maximum tolerated dose of the oral form of rucaparib in combination with intravenous platinum chemotherapy in the treatment of solid tumors. We are obligated under the license agreement to use commercially reasonable efforts to develop and commercialize rucaparib, and with the exception of transfer to us, without cost, of Pfizer's existing inventory of rucaparib, we are responsible for all remaining development and commercialization costs for rucaparib. When and if commercial sales of rucaparib begin, we will pay Pfizer tiered royalties at a mid-teen percentage rate on our net sales, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize rucaparib. We are required to make regulatory milestone payments to Pfizer of up to $89.0 million if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are obligated to make sales milestone payments to Pfizer if specified annual sales targets for rucaparib are met, the majority of which relate to annual sales targets of $500.0 million and above, which, in the aggregate, could amount to total milestone payments of $170.0 million.

The license agreement with Pfizer will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to Pfizer, determined on a product-by-product and country-by-country basis, unless we elect to terminate the license agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Pfizer can terminate the agreement, resulting in a loss of our rights to rucaparib and an obligation to assign or license to Pfizer any intellectual property rights or other rights we may have in rucaparib, including our regulatory filings, regulatory approvals, patents and trademarks for rucaparib.

Ventana Medical Systems, Inc.

In March 2010, we entered into an agreement with Ventana with respect to the development and commercialization of an IVD to measure tissue hENT1 expression and enable prospective classification of patients as either hENT1-high or hENT1-low. Ventana will develop a hENT1 IHC assay, seek FDA approval of a PMA for the IVD, arrange for the manufacture of the hENT1 IHC assay and develop a commercialization strategy for the hENT1 IHC assay. We will provide Ventana the access and data necessary for the PMA IVD submission. We are responsible for the costs and expenses associated with the development of the companion diagnostic. The companion diagnostic will be owned by Ventana, subject to certain rights we may retain in the event Ventana does not commercialize such companion diagnostic, and all revenues generated from the sale of the companion diagnostic will be retained by Ventana. The agreement has a three-year term. Either party may terminate the agreement for any reason upon prior written notice to the other party or immediately upon a material breach of the agreement by the other party that is not cured within a specified time or upon the other party's insolvency or bankruptcy.

Roche Molecular Systems, Inc.

In April 2011, we entered into an agreement with Roche with respect to the development and commercialization of a companion diagnostic test to detect and identify EGFR mutations, including the T790M mutation, in human samples. The companion diagnostic will be developed in stages pursuant to a mutually agreed development plan. Roche will be responsible for the technical development of the EGFR assay, including software development, technical validation and verification of the EGFR assay, clinical reproducibility studies of the EGFR assay and the manufacturability of the EGFR assay. We will be responsible for the validation of the clinical utility of the EGFR assay. We and Roche will jointly promote the EGFR assay once it is commercialized by Roche. We share with Roche the costs and expenses of the development of the companion diagnostic. We may terminate the agreement upon prior written notice to Roche. Roche may terminate the agreement if we breach any of our material obligations under the agreement and are unable to cure such breach within specified time periods or if we were to liquidate, dissolve, wind-up our business or be declared insolvent or bankrupt. The companion diagnostic will be owned by Roche and all revenues generated from the sale of the companion diagnostic will be retained by Roche.

Government Regulation

Government authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of pharmaceutical products, such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with cGMP regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational drug product to humans.

The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal studies or other human studies, as appropriate, as well as manufacturing information, analytical data and any available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices, or GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

- *Phase I.* Phase I includes the initial introduction of an investigational new drug into humans. Phase I clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase II clinical trials. The total number of participants included in Phase I clinical trials varies, but is generally in the range of 20 to 80.
- *Phase II.* Phase II includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase II clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.
- *Phase III.* Phase III clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product, and to provide an adequate basis for product approval. Phase III clinical trials usually involve several hundred to several thousand participants.

A pivotal study is a clinical study which adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are also Phase III studies but may be Phase II studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

The FDA , the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications.

The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

Once the NDA submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug.

After regulatory approval of a drug product is obtained, we are required to comply with a number of post-approval requirements. As a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Available Special Regulatory Procedures

Formal Meetings

We are encouraged to engage and seek guidance from health authorities relating to the development and review of investigational drugs, as well as marketing applications. In the United States, there are different types of official meetings that may occur between us and the FDA. Each meeting type is subject to different procedures. Conclusions and agreements from each of these meetings are captured in the official final meeting minutes issued by the FDA.

The EMA also provides the opportunity for dialogue with us. This is usually done in the form of Scientific Advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each Scientific Advice meeting.

Advice from either the FDA or EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Such advice is not legally binding on the sponsor. To obtain binding commitments from health authorities in the United States and the European Union, SPA or Protocol Assistance procedures are available. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement with the sponsor that the protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. The FDA's agreement to an SPA is binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union Community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of 7 years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug or biological product approval. This period may be reduced to 6 years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan dug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Pediatric Development

In the United States, the FDCA provides for an additional 6 months of marketing exclusivity for a drug if reports are filed of investigations studying the use of the drug product in a pediatric population in response to a written request from the FDA. Separate from this potential exclusivity benefit, NDAs must contain data (or a proposal for post-marketing activity) to assess the safety and effectiveness of an investigational drug product for the claimed indications in all relevant pediatric populations in order to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers if certain criteria are met. Discussions about pediatric development plans can be discussed with the FDA at any time, but usually occur any time between the end-of-Phase II meeting and submission of the NDA.

For the EMA, a Pediatric Investigation Plan, and/or a request for waiver or deferral, is required for submission prior to submitting a marketing authorization application.

Authorization Procedures in the European Union

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure*. The EMA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization issued by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.
- For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.
- *National authorization procedures.* There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:
- *Decentralized procedure.* Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.
- *Mutual recognition procedure.* In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Priority Review/Standard Review (United States) and Accelerated Review (European Union)

Based on results of the Phase III clinical trial(s) submitted in an NDA, upon the request of an applicant, the FDA may grant the NDA a priority review designation, which sets the target date for FDA action on the application at six months. Priority review is granted where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. If criteria are not met for priority review, the NDA is subject to the standard FDA review period of 10 months. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease (e.g. heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare beneficiaries, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Further, the Healthcare Reform Law substantially changes the way healthcare is financed in the United States by both government and private insurers. Among other cost containment measures, the Healthcare Reform Law establishes:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;

- A new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period (the "donut hole"); and
- A new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

We expect that federal, state and local governments in the United States will continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as the drug candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

If we obtain regulatory approval for any of our product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The reach of the Anti-Kickback Statute was broadened by the Healthcare Reform Law, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Healthcare Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The "qui tam" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

In addition, we may be subject to, or our marketing activities may be limited by, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and their business associates governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information.

Regulation of Diagnostic Tests

In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Diagnostic tests are classified as medical devices under the FDCA. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. Because the diagnostic tests being developed by our third-party collaborators are of substantial importance in preventing impairment of human health, they are subject to the PMA approval process.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

We and our third-party collaborators who are developing the companion diagnostics will work cooperatively to generate the data required for submission with the PMA application, and will remain in close contact with the Center for Devices and Radiological Health, or CDRH, at FDA to ensure that any changes in requirements are incorporated into the development plans. We anticipate that meetings with the FDA with regard to our drug product candidates as well as companion diagnostic product candidates will include representatives from the Center for Drug Evaluation and Research, or CDER, and CDRH to ensure that the NDA and PMA submissions are coordinated to enable FDA to conduct a parallel review of both submissions. On July 14, 2011, the FDA issued for comment a draft guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices". According to the draft guidance, for novel therapeutic products such as our product candidates, the PMA for a companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic. While this draft guidance is not yet finalized, we believe our programs for the development of our companion diagnostics are consistent with the draft guidance as proposed.

In the EEA, in vitro medical devices are required to conform with the essential requirements of the E.U. Directive on in vitro diagnostic medical devices (Directive No 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA. The data generated for the U.S. registration will be sufficient to satisfy the regulatory requirements for the European Union and other countries.

Patents and Proprietary Rights

The proprietary nature of, and protection for, our product candidates, processes and know-how are important to our business. Our success depends in part on our ability to protect the proprietary nature of our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. We seek patent protection in the United States and internationally for our product candidates and other technology. Our policy is to patent or in-license the technology, inventions and improvements that we consider important to the development of our business. We also rely on trade secrets, know-how and continuing innovation to develop and maintain our competitive position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology.

We have an exclusive, worldwide license from Clavis to a portfolio of patents related to CO-101. United States Patent 6,384,019 and its equivalent counterparts in 32 other countries, directed to the CO-101 composition of matter, expire in 2018 and are potentially eligible for up to five years patent term extension in various jurisdictions. We believe that patent term extension under the Hatch-Waxman Act could be available to extend our patent exclusivity for CO-101 to at least 2020-2021 in the United States depending on timing of our first approval. In Europe, we believe that patent term extension under a supplementary protection certificate could be available for an additional five years to 2023. A patent application directed to the CO-101 formulation is pending in the United States, PCT, and Taiwan and, if issued, would expire in 2030. We and Clavis have also filed patent applications for various aspects related to CO-101 administration and diagnostics to assess hENT1 levels.

We acquired an exclusive, worldwide license to CO-1686 from Avila in May 2010. Multiple patent applications are pending that claim CO-1686 generically and specifically (including with respect to composition of matter) that, if issued, would have expiration dates between 2029 and 2031.

We obtained an exclusive, worldwide license from Pfizer to develop and commercialize rucaparib in June 2011. U.S. Patent 6,495,541, and its equivalent counterparts issued or pending in dozens of countries, directed to the rucaparib composition of matter, expire in 2020 and are potentially eligible for up to five years patent term extension in various jurisdictions. We believe that patent term extension under the Hatch-Waxman Act could be available to extend our patent exclusivity for rucaparib to at least 2022-2024 in the United States depending on timing of our first approval. In Europe, we believe that patent term extension under a supplementary protection certificate could be available for an additional five years to 2025. Additionally, other patents and patent applications are directed to methods of making, methods of using, dosing regimens, and various salt and polymorphic forms have expiration dates ranging from 2020 through 2031.

We are aware of a family of patents and patent applications controlled by a third party that claim certain uses of PARP inhibitors that could potentially be asserted against our use of rucaparib in certain indications. We are conducting clinical trials for the treatment of solid tumors, a subset of which are ovarian cancer and breast cancer characterized as having positive germ-line BRCA mutations. Methods for treating such germ-line BRCA mutant positive patients with rucaparib could potentially fall within the scope of the issued or to be issued claims of such patents or patent applications. We are evaluating the validity of the patents and patent applications, including the scope or potential scope of the claims of these patents and patent applications, to determine whether to seek a license under such patents or patent applications, when and if they issue, or alternatively whether to initiate proceedings to challenge such patents. If we are unable to either license or successfully challenge such patents, we may consider shifting our development emphasis among alternative uses, and in so doing we could reduce the size of the aggregate potential market for rucaparib.

In addition, we intend to seek patent protection whenever available for any products or product candidates and related technology we acquire in the future.

The patent positions of pharmaceutical firms like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of the product candidates we acquire or license will gain patent protection or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. PTO or a foreign patent office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using specific compounds or technology. To the extent prudent, we intend to bring litigation against third parties that we believe are infringing one or more of our patents.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. PTO in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent.

The patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products.

To protect our rights to any of our issued patents and proprietary information, we may need to litigate against infringing third parties, or avail ourselves of the courts or participate in hearings to determine the scope and validity of those patents or other proprietary rights. These types of proceedings are often costly and could be very time-consuming to us, and we cannot assure you that the deciding authorities will rule in our favor. An unfavorable decision could allow third parties to use our technology without being required to pay us licensing fees or may compel us to license needed technologies to avoid infringing third-party patent and proprietary rights. Such a decision could even result in the invalidation or a limitation in the scope of our patents or forfeiture of the rights associated with our patents or pending patent applications.

In addition we have sought and intend to continue seeking orphan drug status whenever it is available. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the United States and ten years in the European Union. Orphan drug designation does not prevent competitors from developing or marketing different drugs for an indication.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. However, we believe that the substantial costs and resources required to develop technological innovations will help us to protect the competitive advantage of our products.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Manufacturing

We currently contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and intend to do so in the future. We have not entered into long-term agreements with our current contract manufacturers. We currently obtain our supplies of finished drug product through individual purchase orders. We do not own or operate manufacturing facilities for the production of clinical quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for commercial manufacturing, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers. Although we rely on contract manufacturers, we have personnel with extensive manufacturing experience to oversee the relationships with our contract manufacturers.

One of our contract manufacturers has manufactured what we believe to be sufficient quantities of CO-101's active pharmaceutical ingredient (or drug substance) to complete the ongoing clinical trials. We have engaged a second drug substance manufacturer to ensure continuity of supply and to increase overall production capacity. Improvements to the current drug substance manufacturing process are being implemented to further ensure production capacity adequate to meet future development and commercial demands. Another of our existing contract manufacturers continues to produce CO-101 drug product for use in ongoing clinical trials. We are implementing scale-up operations at this manufacturing site to provide additional quantities of CO-101 drug product. We have also identified a second drug product contract manufacturer to provide further capacity for clinical and commercial production. In addition, a separate contract manufacturer labels, packages and distributes clinical supplies of CO-101. We believe the manufacturing processes for the active pharmaceutical ingredient and finished drug product for CO-101 have been developed to adequately support future development and commercial demands. While we believe that our existing suppliers of active pharmaceutical ingredient and drug product would be capable of continuing to produce materials in commercial quantities, we may need to identify additional third-party manufacturers capable of providing commercial quantities of drug product. If we are unable to arrange for such a third-party manufacturing source, or fail to do so on commercially reasonable terms, we may not be able to successfully produce and market CO-101.

The process for producing CO-1686 active pharmaceutical ingredient is currently being developed at a single third-party contract manufacturer. The current process has already been sufficiently developed to satisfy immediate clinical demands. Additional process development work and/or additional production capacity may be necessary to support larger clinical development or commercialization requirements. If we are unable to adequately develop a suitable process, or arrange for such a third-party manufacturing source, or fail to do so on commercially reasonable terms, we may not be able to successfully produce and market CO-1686. Drug product formulation development work for CO-1686 is in progress. We have engaged a third-party manufacturer capable of both formulation development and drug product manufacturing. Definition of an acceptable formulation and suitable manufacturing process to prepare that formulation are critical to the successful development of CO-1686. If we fail to define such a formulation and process, or fail to do so on commercially reasonable terms, we may be unable to successfully produce and market CO-1686.

We have developed the process for manufacturing rucaparib's active pharmaceutical ingredient to a degree sufficient to meet clinical demands and projected commercial requirements. Pfizer is currently performing manufacturing for rucaparib. Although we believe the licensor has available quantities of the active pharmaceutical ingredient to permit current production sufficient to allow us to conclude the currently pending trials for rucaparib, we will need to identify an alternate third-party contract manufacturer for preparation of the rucaparib active pharmaceutical ingredient. While we believe that sufficient capacity and capabilities for manufacture of this compound exists, failure to arrange such a third-party source, or failure to do so on commercially reasonable terms may prevent successful production and marketing of rucaparib. The rucaparib drug product formulation and manufacturing process to produce that formulation have been developed to a degree sufficient to meet clinical demands and projected commercial requirements. While Pfizer will turn over to us its existing inventory of finished dosage form of rucaparib, and produce additional quantities for us, we will need to identify an alternate third-party contract manufacturer for preparation of rucaparib in finished dosage form. While we believe that sufficient capacity and capabilities for manufacture of this formulation exists, failure to arrange such a third-party source, or failure to do so on commercially reasonable terms may prevent successful production and marketing of rucaparib.

To date, our third-party manufacturers have met our manufacturing requirements. We expect third-party manufacturers to be capable of providing sufficient quantities of our product candidates to meet anticipated full scale commercial demands. We believe that there are alternate sources of supply that can satisfy our clinical and commercial requirements, although we cannot be certain that identifying and establishing relationships with such sources, if necessary, would not result in significant delay or material additional costs.

Sales and Marketing

We intend to build the commercial infrastructure in the United States and Europe necessary to effectively support the commercialization of CO-101, CO-1686, and rucaparib if and when we believe a regulatory approval of the first of such product candidates in a particular geographic market appears imminent. The commercial infrastructure for oncology products typically consists of a targeted, specialty sales force that calls on a limited and focused group of physicians supported by sales management, internal sales support, an internal marketing group and distribution support. Additional capabilities important to the oncology marketplace include the management of key accounts such as managed care organizations, group-purchasing organizations, specialty pharmacies, oncology group networks, and government accounts. To develop the appropriate commercial infrastructure, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that CO-101, CO-1686, or rucaparib will be approved.

Outside of the United States and Europe, where appropriate, we may elect in the future to utilize strategic partners, distributors, or contract sales forces to assist in the commercialization of our products. We are actively considering an Asian commercial presence, including establishing our own sales and marketing organization in Japan.

Employees

As of March 12, 2012, we had 57 full-time employees. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Research and Development

We invested $40.7 million, $22.3 million and $1.8 million in research and development in the years ended December 31, 2011 and 2010, and the period from April 20, 2009 (inception) through December 31, 2009, respectively.

About Clovis

We were incorporated under the laws of the State of Delaware in April 2009 by former executives of Pharmion Corporation, which successfully developed and commercialized novel oncology products in the United States and Europe and was ultimately acquired by Celgene Corporation in 2008. Our initial investors included the following entities or their affiliates: Domain Associates, New Enterprise Associates, Versant Ventures, Aberdare Ventures, Abingworth Bioventures, Frazier Healthcare Ventures, Pfizer Inc., ProQuest Investments and our management team. We completed our initial public offering of our common stock in November 2011, and our common stock is listed on the NASDAQ Global Select Market, under the symbol “CLVS”. Our principal executive offices are located at 2525 28th Street, Suite 100, Boulder, Colorado 80301, and our telephone number is (303) 625-5000. Our website address is *www.clovisoncology.com.* Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this report.

Available Information

As a public company, we file reports and proxy statements with the Securities and Exchange Commission, or the SEC. These filings include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements on Schedule 14A, as well as any amendments to those reports and proxy statements, and are available free of charge through our website as soon as reasonably practicable after we file them with, or furnish them to, the SEC. Once at *www.clovisoncology.com*, go to Investor Relations/SEC Filings to locate copies of such reports. You may also read and copy materials that we file with SEC at the SEC’s Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website at *www.sec.gov* that contains reports, proxy and information statements and other information regarding us and other issuers that file electronically with the SEC.

ITEM 1A. RISK FACTORS

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We are a clinical-stage company with no approved products, and no historical revenues, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have focused primarily on in-licensing and developing our product candidates, CO-101, CO-1686 and rucaparib. We are not profitable and have incurred losses in each year since our inception in April 2009. Because we were only recently formed, we have only a limited operating history upon which you can evaluate our business and prospects. In addition, as an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. We have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. For the years ended December 31, 2011 and 2010 and period from April 20, 2009 (inception) to December 31, 2009, we had net losses of $55.5 million, $37.8 million and $17.1 million, respectively. As of December 31, 2011, we had an accumulated deficit of $110.4 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. As such, we are subject to all of the risks incident in the development of new biopharmaceutical products and related companion diagnostics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets.

We will require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. We will also require funding for our other operating expenses as well as capital expenditures to maintain and improve our facilities, equipment and systems.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our three product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Two of our product candidates, CO-101 and rucaparib, are in clinical trials, while our third product candidate, CO-1686, is expected to enter clinical trials during the second quarter of 2012. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

Each of our product candidates will require additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We believe that, depending on the result of our current CO-101 clinical trial, this trial may serve as a pivotal trial to support our application for approval of CO-101. To the extent that the results of the trial are not satisfactory to the FDA or the EMA for support of an NDA or MAA, respectively, with respect to CO-101, we will be required to expend significant additional resources to conduct additional clinical trials in support of approval of CO-101. In addition, our product development programs contemplate the development of companion diagnostics by our third-party collaborators. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates.

We have not previously submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States, the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in clinical trials for CO-101 and rucaparib do not ensure that later clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

Although we have clinical trials ongoing for CO-101 and rucaparib, and although we are planning to initiate clinical trials for CO-1686 in the second quarter of 2012, we may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- developing and validating companion diagnostics on a timely basis;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market CO-101, rucaparib and CO-1686, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. To date, patients treated with CO-101 have experienced drug-related side effects including nausea, vomiting, anorexia, fatigue, myelosuppression (an impairment of bone marrow function), neutropenia (a reduction in white blood cells), and thrombocytopenia (a reduction in blood platelet cells) and those treated with rucaparib have experienced drug-related side effects such as nausea and vomiting. While we have not yet initiated clinical trials for CO-1686, as is the case with all oncology drugs, it is likely that there may be side effects associated with its use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy.

As one of the key elements of our clinical development strategy, we seek to identify patient subsets within a disease category who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with partners, we plan to develop companion diagnostics to help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidates. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We do not develop companion diagnostics internally, and thus we are dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

If we established the hENT1 cut-off improperly, or if our LEAP trial results do not support the hENT1 hypothesis, we could jeopardize our potential for success with CO-101.

Retrospective analysis of tissue samples has shown a correlation between hENT1 expression levels and response to gemcitabine therapy such that patients with low levels of hENT1 expression are believed to derive little or no benefit from the drug. Our ongoing pivotal trial will, to our knowledge, be the first clinical trial to prospectively identify patients as hENT1-low and to then correlate their response to CO-101 versus gemcitabine. We utilized both previously published research data, as well as the data we derived from our own retrospective analysis of tissue samples, to reach a judgment as to those pancreatic cancer patients whose level of hENT1 expression we characterize as "hENT1-low". Using this definition of hENT1-high and hENT1-low, 65% of the first 250 patients enrolled in the LEAP trial have been classified as hENT1-low. If we have set the cut-off too high (to cover a broader range of patients), we may reduce our chances of being able to show a statistically significant improvement in the rate of survival in the patients classified as hENT1-low, and thereby fail to meet the pre-defined endpoint of the trial. Conversely, if we were overly conservative in our judgment of classifying patients as hENT1-low, we may improve our chance of success in achieving the pre-defined endpoint, but at the cost of limiting the prescribing label on CO-101 to such a small subset of potential patients as to significantly constrain the commercial potential for this product candidate, if approved. Finally, we have established our hENT1 cut-off based on tissue samples that came from primary pancreatic tumors, but are using tissue samples from metastatic cancer sites to define the hENT1 status of the patients in the trial. While there are limited data that suggest that the hENT1 status is generally consistent between metastatic and primary tumors, this may not be the case in the clinical setting, which could adversely affect the outcome of the trial.

There have been multiple publications addressing the relationship between hENT1 levels and gemcitabine treatment outcomes. To date, all of these publications have suggested the same relationship, namely that hENT1-high patients tend to respond better to gemcitabine therapy than hENT1-low patients. For example, in 2009, a study published in Gastroenterology reported the results of a retrospective analysis of randomized samples collected from 198 pancreatic cancer patients between 1998 and 2002 comparing treatment with gemcitabine versus 5-FU. Patients in this study treated with gemcitabine who had a high level of hENT1 expression had a median overall survival of 21 months, compared to a median overall survival of 16 months for gemcitabine-treated patients with low hENT1 expression and 12 months for gemcitabine-treated patients with no hENT1 expression. Importantly, the results of this study also demonstrated that there was no correlation between overall survival and hENT1 expression for patients treated with 5-FU. It is possible that other retrospective analyses of tissue samples may be published that do not reflect this correlation. Moreover, none of such studies have attempted to do what our LEAP trial is designed to do, which is to seek to prospectively prove this hENT1 hypothesis. Accordingly, we bear the risk that in a prospective, well controlled clinical trial, we may not be able to prove the hENT1 hypothesis. Our failure to achieve the predefined endpoints of the LEAP trial that support this hENT1 hypothesis would have an adverse impact on our ability to obtain approval for CO-101 and on our business, financial condition and prospects.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current good clinical practices, or cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely completely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, Competent Authorities of the Member States of the EEA or comparable regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practices, or cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product 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 product candidates.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. We have not entered into long-term agreements with our current contract manufacturers or with any alternate fill/finish suppliers, and though we intend to do so prior to commercial launch in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. We currently obtain our supplies of finished drug product through individual purchase orders.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we 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 may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We currently have no marketing and sales organization. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any product candidates, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to our product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.

Even if we obtain regulatory approval for our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the potential and perceived advantages of such product candidate over alternative treatments, especially with respect to patient subsets that we are targeting with such product candidate;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, health care payors and patients, we will not be able to generate significant revenues, and we may not become or remain profitable.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the oncology market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, there are currently two agents approved for the treatment of metastatic pancreatic cancer: Gemzar®/gemcitabine marketed by Eli Lilly, Teva Pharmaceutical Industries and APP Pharmaceuticals, and Tarceva® (erlotinib) marketed by Astellas Pharma, and there are a number of active clinical trials ongoing in pancreatic cancer, including by AB Science SA, Amgen Inc., Astellas Pharma, BioSante Pharmaceuticals, Inc., Celgene Corporation, Immunomedics, Inc., Lorus Therapeutics, Merrimack Pharmaceuticals, Inc., NewLink Genetics Corporation, and Threshold Pharmaceuticals, Inc. Tarceva® and Iressa® are two of the currently approved drugs that are used to treat EGFR mutant NSCLC, and in addition, we are aware of two products in development targeting EGFR for the treatment of NSCLC: Boehringer Ingelheim's BIBW-2992 (afatinib) and Pfizer's PF-299804. Finally, we believe the products in development targeting the PARP pathway consist of Abbott's ABT-888 (velaparib), Merck's MK-4827, Eisai's E-7016, Cephalon's CEP-9722 and Biomarin's BMN-673.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products that are more effective or less costly than any drug candidate that we are currently developing or that we may

develop. If approved, our product candidates will face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors and later enter the market if approved.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. We intend to seek approval to market our product candidates in the United States, Europe and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under the Medicare program in the United States. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the Healthcare Reform Law of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, beginning in 2011;
- an increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, under which manufacturers must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in 2011;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective January 2010;
- a licensure framework for follow-on biologic products; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any drug products for which we may obtain regulatory approval;
- our ability to set a price for our products;
- the demand for any drug products for which we may obtain regulatory approval;
- our ability to generate revenues and achieve or maintain profitability;

- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, especially Patrick J. Mahaffy, our President and Chief Executive Officer, Erle T. Mast, our Executive Vice President and Chief Financial Officer, Andrew R. Allen, our Executive Vice President of Clinical and Pre-Clinical Development and Chief Medical Officer, and Gillian C. Ivers-Read, our Executive Vice President, Technical Operations and Chief Regulatory Officer, whose services are critical to the successful implementation of our product candidate acquisition, development and regulatory strategies. We are not aware of any present intention of any of these individuals to leave our company. In order to induce valuable employees to continue their employment with us, we have provided stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Pursuant to their employment arrangements, each of our executive officers may voluntarily terminate their employment at any time by providing as little as thirty days advance notice. Our employment arrangements, other than those with our executive officers, provide for at-will employment, which means that any of our employees (other than our executive officers) could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of March 12, 2012, we had 57 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- expanding our facilities.

As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenues from product sales; and
- the inability to commercialize our product candidates.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry $10.0 million of product liability insurance, which we believe is adequate for our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

We have incurred substantial losses during our history and do not expect to become profitable in 2012 and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2011, we had federal net operating loss carryforwards of approximately $63.6 million that could be limited if we experience an ownership change, which could have an adverse effect on our results of operations.

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

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

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm our results of operations.

In recent years, there have been several changes in laws, rules, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and various other new regulations promulgated by the SEC and rules promulgated by the national securities exchanges.

The Dodd-Frank Act, enacted in July 2010, expands federal regulation of corporate governance matters and includes significant corporate governance and executive compensation-related provisions that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. The SEC has since issued final rules implementing "say on pay" measures. We expect these rules and regulations to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Further, compliance with new and existing laws, rules, regulations and standards may make it more difficult and expensive for us to maintain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers, which could harm our business. We continually evaluate and monitor regulatory developments and cannot estimate the timing or magnitude of additional costs we may incur as a result.

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or the U.S. PTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

With respect to CO-101, we have an exclusive, worldwide license from Clavis to a portfolio of patents directed to the CO-101 composition of matter that expire in 2018. With respect to rucaparib, we have an exclusive, worldwide license from Pfizer to a portfolio of patents and patent applications directed to the rucaparib composition of matter that expire in 2020. While patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend our patent exclusivity for either CO-101 or rucaparib, we cannot provide any assurances that any such patent term extension will be obtained.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including interference and reexamination proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

We are aware of a family of patents and patent applications controlled by a third party that claim certain uses of PARP inhibitors that could potentially be asserted against our use of rucaparib in certain indications. We are conducting clinical trials for the treatment of solid tumors, a subset of which are ovarian cancer and breast cancer characterized as having positive germ-line BRCA mutations. Methods for treating such germ-line BRCA mutant positive patients with rucaparib could potentially fall within the scope of the issued or to be issued claims of such patents or patent applications. We are evaluating the validity of the patents and patent applications, including the scope or potential scope of the claims of these patents and patent applications, to determine whether to seek a license under such patents or patent applications, when and if they issue, or alternatively whether to initiate proceedings to challenge such patents. If we are unable to either license or successfully challenge such patents, we may consider shifting our development emphasis among alternative uses, and in so doing we could reduce the size of the aggregate potential market for rucaparib.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

The patent protection and patent prosecution for some of our product candidates is dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when platform technology patents that relate to our product candidates are controlled by our licensors. This is the case with our license of CO-1686 from Avila Therapeutics, Inc., in which Avila retained the right to prosecute and maintain the patents and patent applications covering its core discovery technology, including molecular backbones, building blocks and classes of compounds generated by that technology, aspects of which relate to CO-1686. While we have the right to prosecute and maintain the patent rights for the composition of matter for CO-1686, if Avila or any of our future licensing partners fail to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

If we breach any of the agreements under which we license commercialization rights to our product candidates from third parties, we could lose license rights that are important to our business.

We license the use, development and commercialization rights for all of our product candidates, and may enter into similar licenses in the future. Under each of our existing license agreements with Clavis (CO-101), Avila (CO-1686) and Pfizer (rucaparib), we are subject to commercialization and development, diligence obligations, milestone payment obligations, royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensing partners may have the right to terminate the license in whole or in part. Generally, the loss of any one of our three current licenses or other licenses in the future could materially harm our business, prospects, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Ownership of our Common Stock

The price of our common stock may be volatile, and your shares may suffer a decline in value.

As a biopharmaceutical company with no products currently on the market, the trading price of our common stock may be subject to wide fluctuations in response to various factors discussed in this "Risk Factors" section, and others beyond our control, including:

- our failure to commercialize our product candidates, if approved;
- actual or anticipated adverse results or delays in our clinical trials;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our dependence on third parties, including CROs as well as our partners that provide us with companion diagnostic products;
- additions or departures of key scientific or management personnel;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- significant lawsuits, including patent or stockholder litigation;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- ineffectiveness of our internal controls;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the NASDAQ Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of March 12, 2012, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 65.1% of our outstanding voting stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we will be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report, commencing in our annual report on Form 10-K for the year ending December 31, 2012, on the effectiveness of our internal controls over financial reporting, if then required by Section 404 of the Sarbanes-Oxley Act. Compliance with Section 404 of the Sarbanes Oxley Act also requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting. Prior to becoming a public company, we were not required to comply with Section 404 of the Sarbanes-Oxley Act, and as a result we have not yet fully evaluated our compliance with these provisions. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, investors may lose confidence in our operating results, and the market price of our stock could decline and we could be subject to sanctions or investigations by the NASDAQ Stock Market, the SEC or other regulatory authorities, which would require additional financial and management resources.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lapse of lock-up restrictions on resale resulting from our initial public offering and any other legal restrictions on resale, the trading price of our common stock could decline.

We expect that the lock-up agreements pertaining to our initial public offering will expire on May 14, 2012 (subject to extension upon the occurrence of specified events). As of March 12, 2012, after the lock-up agreements expire, up to an additional 15,947,996 shares of common stock, subject to vesting schedules, will be eligible for sale in the public market, 11,882,945 of which shares are held by directors, executive officers and other affiliates and will be subject to vesting schedules, volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. Our underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Furthermore, 15,721,106 shares of our common stock, or approximately 70.3% of our total outstanding common stock as of March 12, 2012 (and holders of 297,237 shares of our common stock issuable upon exercise of options to purchase our common stock), are entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules and to the lock-up agreements described above). Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plan(s), our compensation committee (or a subset thereof) is authorized to grant equity-based incentive awards to our employees, directors and consultants. As of December 31, 2011, the number of shares of our common stock available for future grant under our 2011 Equity Incentive Plan, or the 2011 Plan, is 1,357,258, which includes 138,258 shares of our common stock that were reserved for future issuance under our the 2009 Equity Incentive Plan, or the 2009 Plan, and were transferred to the 2011 Plan for future issuance. The number of shares of our common stock reserved for issuance under our 2011 Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under our 2009 Plan, and (ii) at the discretion of our board of directors, on the date of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 4% of our then-outstanding shares of common stock on such date and (y) 2,758,621 shares of our common stock. Future option grants and issuances of common stock under our 2011 Plan may have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 2. PROPERTIES

Our offices are located at three leased facilities, a 10,369 square foot facility in Boulder, Colorado used primarily for corporate functions, a 17,195 square foot facility in San Francisco, California used for clinical development operations and research laboratory space, and a 1,050 square foot facility in Cambridge, United Kingdom used for our European regulatory and clinical operations. These leases expire in December 2015, May 2013, and May 2012, respectively. We believe that our existing facilities are sufficient for our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

We are not currently 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 STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock is traded on the NASDAQ Global Select Market under the symbol "CLVS." Trading of our common stock commenced on November 16, 2011, following the completion of our initial public offering. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on the NASDAQ Global Select Market:

Year Ended December 31, 2011	HIGH	LOW
Fourth Quarter (beginning November 16, 2011)	$14.85	$11.45

On March 12, 2012, there were approximately 45 holders of record of our common stock.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information
As of December 31, 2011

Plan Category	Number of securities to be issued upon exercise of outstanding options and rights (a)	Weighted- average exercise price of outstanding options and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)(2)	934,816	$ 4.88	1,546,914
Equity compensation plans not approved by security holders	—	—	—
Total	934,816	$ 4.88	1,546,914

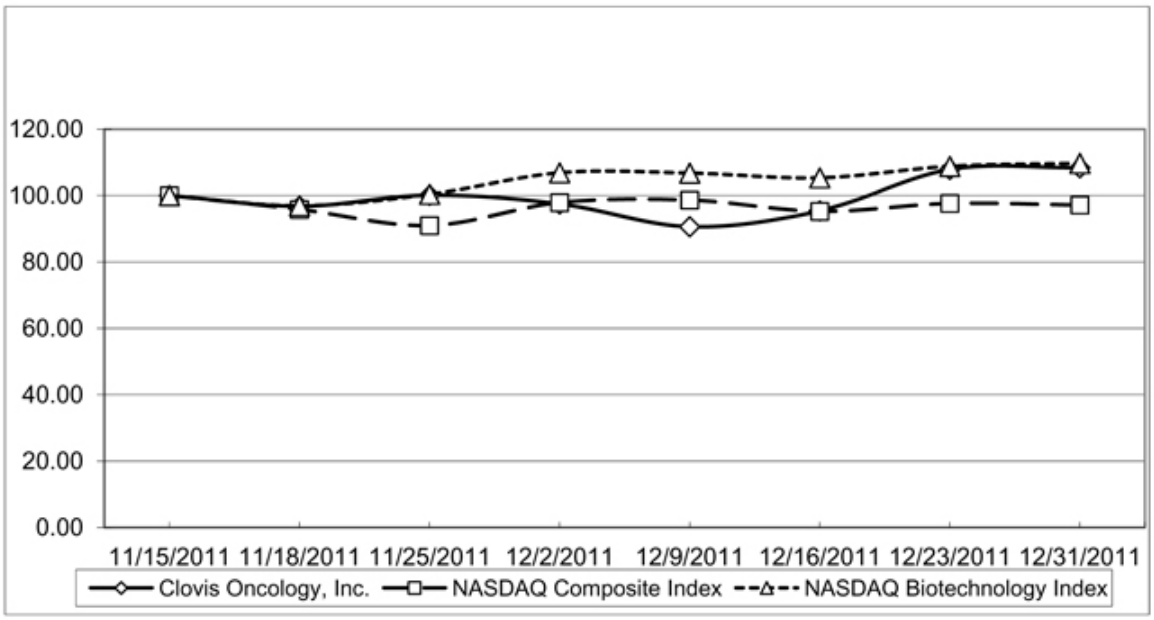
(1) As of December 31, 2011, 1,388,258 shares were authorized for issuance under our 2011 Stock Incentive Plan, or the 2011 Plan, which became effective on November 15, 2011, the effective date of our initial public offering, including 138,258 remaining shares available for future issuance under the 2009 Equity Incentive Plan, or 2009 Plan, which were transferred to the 2011 Plan. The number of shares of our common stock reserved for issuance under the 2011 Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under the 2009 Plan, and (ii) at the discretion of our board of directors, on the date of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 4% of our then-outstanding shares of common stock on such date and (y) 2,758,621 shares of our common stock.

(2) As of December 31, 2011, 189,656 shares were reserved for issuance under our 2011 Employee Stock Purchase Plan, or ESPP, which became effective on November 15, 2011, the effective date of our initial public offering. The number of shares of our common stock reserved for issuance under the ESPP will be increased at the discretion of our board of directors, on the date of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 1% of our then-outstanding shares of common stock on such date and (y) 344,828 shares of our common stock.

Performance Graph[1]

The following graph shows a comparison from November 16, 2011 through December 31, 2011 of cumulative total return on assumed investment of $100.00 in cash in our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and the NASDAQ Biotechnology Index assume reinvestment of dividends.

COMPARISON OF 7 WEEK CUMULATIVE TOTAL RETURN
Among Clovis Oncology, Inc., the NASDAQ Cumulative Index, and the NASDAQ Biotechnology Index



[1] *This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section, and shall not be deemed incorporated by reference into any filing of Clovis Oncology, Inc. under the Securities Act of 1933, as amended.*

Recent Sales of Unregistered Securities

Set forth below is information regarding certain shares of common stock and preferred stock issued by us within the past three years that were not registered under the Securities Act of 1933, as amended, which we refer to as the Securities Act. Also included is the consideration, if any, received by us for such shares and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(1) On May 12, 2009, we sold an aggregate of 1,206,899 shares of our common stock at a price per share of $0.0029 to accredited investors, for an aggregate purchase price of $3,500.

(2) On May 15, 2009, we sold an aggregate of 5,044,828 shares of our series A-1 convertible preferred stock at a price per share of $2.00 (conversion price of $5.80 per share) to accredited investors, for an aggregate purchase price of $10,089,656.

(3) On November 9, 2009, we sold an aggregate of 5,044,828 shares of our series A-2 convertible preferred stock at a price per share of $3.00 (conversion price of $8.70 per share) to accredited investors, for an aggregate purchase price of $15,134,484.

(4) On November 18, 2009, we sold an aggregate of 10,919,540 shares of our series B convertible preferred stock at a price per share of $4.62 (conversion price of $13.40 per share) to accredited investors, for an aggregate purchase price of $50,448,275.

(5) On May 25, 2011, we sold $20,000,000 aggregate principal amount of our 5% convertible promissory notes due 2012 to accredited investors, for an aggregate purchase price of $20,000,000.

(6) On June 2, 2011, we sold $15,000,000 aggregate principal amount of our 5% convertible promissory notes due 2012 to Pfizer Inc., an accredited investor, $7.0 million of which were issued as consideration for the execution of our license agreement with Pfizer Inc. for rucaparib and $8.0 million of which were issued for an investment of $8.0 million of cash by Pfizer Inc.

(7) From April 20, 2009 through November 15, 2011, we issued an aggregate of 466,547 shares of our common stock at prices ranging from $0.29 to $3.28 per share to certain of our employees and directors pursuant to the exercise of stock options under the Clovis Oncology, Inc. 2009 Equity Incentive Plan for an aggregate purchase price of $1,150,487.

(8) From April 20, 2009 through November 15, 2011, we granted options to purchase 1,384,551 shares of common stock to our employees and directors at a weighted average exercise price of $3.87 per share.

No underwriters were involved in the foregoing issuances of securities. The securities described in paragraphs (1) through (6) above were issued to accredited investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act, and, in certain cases, in reliance on Regulation D promulgated thereunder, relative to transactions by an issuer not involving any public offering, to the

extent an exemption from such registration was required. The securities described in paragraph (7) through (8) above were issued pursuant to written compensatory plans or arrangements with our employees and directors in reliance on the exemption provided by Rule 701 promulgated under Section 3(b) of the Securities Act, or pursuant to Section 4(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. The certificates representing the issued shares of capital stock described above included appropriate legends setting forth that the applicable securities have not been registered and the applicable restrictions on transfer.

Use of Proceeds from Sales of Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-175080) that was declared effective by the Securities and Exchange Commission on November 15, 2011, which registered an aggregate of 11,500,000 shares of our common stock. On November 21, 2011, 10,000,000 shares of common stock were sold on our behalf at an initial public offering price of $13.00 per share, for aggregate gross proceeds of $130,000,000 million, managed by J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC. On November 30, 2011, in connection with the exercise of the underwriters' over-allotment option, 700,000 additional shares of common stock were sold on our behalf at the initial public offering price of $13.00 per share, for aggregate gross proceeds of $9,100,000. Following the sale of the 10,700,000 shares of common stock, the offering terminated.

We paid to the underwriters underwriting discounts and commissions of approximately $6.9 million in connection with the offering. In addition, we incurred expenses of approximately $2.8 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $9.7 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $129.4 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of December 31, 2011, we had used approximately $5.2 million of the net proceeds from our initial public offering to fund operations, capital expenditures, working capital and other general corporate purposes. The remainder of the proceeds have been invested into money market funds.

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth certain of our selected historical financial data at the dates and for the periods indicated. The selected historical statement of operations data presented below for the years ended December 31, 2011, 2010 and the period from April 20, 2009 (inception) to December 31, 2009 and the historical balance sheet data as of December 31, 2011, 2010 and 2009 have been derived from our audited financial statements, which are included elsewhere in this Annual Report on Form 10-K.

The financial information presented from April 20, 2009 (inception) to December 31, 2010 is based solely on the results of Clovis Oncology, Inc. Subsequent to January 1, 2011, the financial information is consolidated and includes the results of our wholly owned subsidiary in the United Kingdom. Our historical results are not necessarily indicative of results expected in any future period.

The selected historical financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes thereto, which are included elsewhere in this Annual Report on Form 10-K. The selected historical financial information in this section is not intended to replace our financial statements and the related notes thereto.

Statement of Operations Data:

	Year Ended December 31,		Period from April 20, 2009 (Inception) to December 31, 2009	Cumulative from April 20, 2009 (Inception) to December 31, 2011
	2011	2010		
	(in thousands, except per share amounts)			
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	40,726	22,323	1,762	64,811
General and administrative	6,860	4,302	2,209	13,371
Acquired in-process research and development	7,000	12,000	13,085	32,085
Operating loss	(54,586)	(38,625)	(17,056)	(110,267)
Other income (expense), net	(957)	795	(43)	(205)
Loss before income taxes	(55,543)	(37,830)	(17,099)	(110,472)
Income taxes	(27)	—	—	(27)
Net loss	$(55,570)	$ (37,830)	$ (17,099)	$(110,499)
Basic and diluted net loss per common share	$ (14.42)	$ (28.55)	$ (15.38)	$ (51.06)
Common shares used in the computation of basic and diluted net loss per common share	3,854	1,325	1,112	2,164

	As of December 31,		
	2011	2010	2009
	(in thousands)		
Balance Sheet Data:			
Cash, cash equivalents and available for sale securities	$ 140,248	$ 22,299	$ 57,311
Working capital	130,519	19,886	57,349
Total assets	143,445	26,200	59,574
Convertible preferred stock	—	75,499	75,499
Common stock and additional paid-in capital	242,243	138	41
Total stockholders' equity (deficit)	131,793	(54,749)	(17,058)

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and seek to simultaneously develop, with partners, companion diagnostics that direct our product candidates to the patients that are most likely to benefit from their use. We are currently developing three product candidates for which we hold global marketing rights: CO-101, a lipid-conjugated form of the anti-cancer drug gemcitabine, which is in a pivotal study in a specific patient population for the treatment of metastatic pancreatic cancer; CO-1686, an orally available, small molecule epidermal growth factor receptor, or EGFR, covalent inhibitor that in the second quarter of 2012 will begin Phase I clinical development for the treatment of non-small cell lung cancer, or NSCLC, in patients with activating EGFR mutations, including the initial activating mutations, as well as the primary resistance mutation, T790M; and rucaparib, also known as CO-338, an orally available, small molecule poly (ADP-ribose) polymerase, or PARP, inhibitor being developed for various solid tumors that is currently in Phase I/II clinical trials. As our product candidates mature, we intend to build commercial organizations of our own in major global markets and contract with local distributors in smaller markets.

We were incorporated in Delaware in April 2009 and commenced operations in May 2009. To date, we have devoted substantially all of our resources to identifying and in-licensing product candidates, performing development activities with respect to those product candidates, and the general and administrative support of these operations. We have generated no revenues and, through December 31, 2011, have principally funded our operations using the $75.5 million of net proceeds from the sale of convertible preferred stock, the issuance of $35.0 million aggregate principal amount of convertible promissory notes and $129.4 million of net proceeds from our initial public offering completed in November 2011. The convertible preferred stock and outstanding principal amount of the convertible promissory notes and all accrued and unpaid interest converted into shares of our common stock immediately prior to the closing of our initial public offering. On September 22, 2011, our Board of Directors and stockholders effectuated a 1 for 2.9 reverse stock split. Our historical share information has been retrospectively adjusted to give effect to this reverse stock split.

We have never been profitable and, as of December 31, 2011, we had an accumulated deficit of $110.5 million. We incurred losses of $17.1 million, $37.8 million, and $55.6 million for the period from April 20, 2009 (inception) through December 31, 2009 and for the years ended December 31, 2010, and 2011, respectively. We expect to incur significant and increasing losses for the foreseeable future as we advance our product candidates through clinical development to seek regulatory approval and, if approved, commercialize such product candidates. We will need additional financing to support our operating activities. We will seek to fund our operations through public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We expect that research and development expenses will increase as we continue the development of our product candidates and general and administrative costs will increase as we grow and operate as a public company. We will need to generate significant revenues to achieve profitability and we may never do so.

The financial information presented from April 20, 2009 (inception) to December 31, 2010 was based solely on the results of Clovis Oncology, Inc. Subsequent to January 1, 2011, the financial information is consolidated and includes the results of our wholly owned subsidiary in the United Kingdom. All intercompany transactions and balances are eliminated in this consolidation.

Product License Agreements

CO-101

In November 2009, we entered into a license agreement with Clavis to develop and commercialize CO-101 in North America, Central America, South America and Europe. Under the terms of the license agreement, we made an up-front payment to Clavis in the amount $15.0 million, which was comprised of $13.1 million for development costs incurred prior to the execution of the agreement, which we recognized as acquired in-process research and development and $1.9 million for the prepayment of preclinical activities to be performed by Clavis. In November 2010, the license agreement was amended to expand the license territory to include Asia and other international markets. We paid Clavis $10.0 million for the territory expansion and recognized that payment as acquired in-process research and development expense. As part of the amendment to the license agreement, Clavis has also agreed to reimburse up to $3.0 million of our research and development costs for certain CO-101 development activities subject to our incurring such costs. We are responsible for all remaining development and commercialization costs of the compound and, if approved, Clavis will be entitled to receive royalties based on the volume of annual net sales achieved. We may be required to pay Clavis an aggregate of up to $115.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we may be required to pay Clavis an aggregate of up to $445.0 million in sales milestone payments if certain annual sales targets are met for CO-101.

Subject to certain conditions set forth in the license agreement, Clavis may elect to co-develop and co-promote CO-101 in Europe. If Clavis were to make this election, it would be required to reimburse us for a portion of both past and future development costs. In addition, our milestone payment obligations described above would be reduced. Clavis would not be entitled to royalties on the net sales in Europe, but would instead share equally in the pretax profits or losses resulting from commercialization activities in Europe.

CO-1686

In May 2010, we entered into a worldwide license agreement with Avila to discover, develop and commercialize preclinical covalent inhibitors of mutant forms of EGFR. CO-1686 was identified as the lead inhibitor candidate developed by Avila under the license agreement. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize CO-1686. We made an up-front payment of $2.0 million to Avila upon execution of the license agreement which we recognized as acquired in-process research and development expense. We are obligated to pay Avila royalties on net sales of CO-1686, based on the volume of annual net sales achieved. Avila has the option to increase royalty rates by electing to reimburse a portion of our development expenses. This option must be exercised within a limited period of time of Avila's being notified by us of our intent to pursue regulatory approval of CO-1686 in the United States or the European Union as a first-line treatment. We may be required to pay Avila up to an aggregate of $119.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we may be required to pay Avila up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

In January 2012, the U.S. Food and Drug Administration accepted our investigational new drug application to begin clinical investigation of CO-1686, which triggered the first development milestone payment to Avila of $4.0 million.

Rucaparib

In June 2011, we entered into a license agreement with Pfizer to acquire exclusive global development and commercialization rights to Pfizer's drug candidate PF-01367338, also known as CO-338 or rucaparib. This drug candidate is a small molecule PARP inhibitor which we are developing for the treatment of selected solid tumors. Pursuant to the terms of the license agreement, we made an up-front payment by issuing Pfizer $7.0 million principal amount of a 5% convertible promissory note due 2012 , which was subsequently converted to common stock immediately prior to our initial public offering. We are responsible for all development and commercialization costs of rucaparib and, if approved, we will be required to pay Pfizer royalties on sales of the product. In addition, we may be required to pay Pfizer up to an aggregate of $259.0 million in milestone payments if certain development, regulatory and sales milestones are achieved.

Financial Operations Overview

Revenue

To date, we have not generated any revenues. In the future, we may generate revenue from the sales of product candidates that are currently under development. Based on our current development plans, we do not expect to generate significant revenues until 2014 at the earliest. If we fail to complete the development of our product candidates and, together with our partners, companion diagnostics or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, will be adversely affected.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of our product candidates and companion diagnostics, which include:

- license fees related to the acquisition of in-licensed products, which are reported on our statements of operations as acquired in-process research and development;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials and preclinical studies;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- costs associated with preclinical activities and regulatory operations; and
- activities associated with the development of companion diagnostics for our product candidates.

Research and development costs are expensed as incurred. License fees and milestone payments related to in-licensed products and technology are expensed if it is determined that they have no alternative future use. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to complete development of our most advanced product candidate, CO-101, and its companion diagnostic, transition our CO-1686 product candidate into human clinical trials, and commence the development of rucaparib including the cost of ongoing clinical trials.

The following table identifies research and development costs and acquired in-process research and development costs on a program-specific basis for our product candidates in-licensed through December 31, 2011 and their companion diagnostics. Personnel-related costs, depreciation and stock-based compensation are not allocated to specific programs as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses in the table below.

	Year Ended December 31, 2011	Year Ended December 31, 2010	Period from April 20, 2009 (Inception) to December 31, 2009	Cumulative from April 20, 2009 (Inception) to December 31, 2011
	(in thousands)			
CO-101 Expenses				
Acquired in-process R&D	$ —	$ 10,000	$ 13,085	$ 23,085
Research and development	21,703	14,461	371	36,535
CO-101 Total	21,703	24,461	13,456	59,620
CO-1686 Expenses				
Acquired in-process R&D	—	2,000	—	2,000
Research and development	6,196	2,432	—	8,628
CO-1686 Total	6,196	4,432	—	10,628
Rucaparib Expenses				
Acquired in-process R&D	7,000	—	—	7,000
Research and development	2,861	—	—	2,861
Rucaparib Total	9,861	—	—	9,861
Personnel and other expenses	9,966	5,430	1,391	16,787
Total	$ 47,726	$ 34,323	$ 14,847	$ 96,896

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, and information technology functions. Other general and administrative expenses include facility costs, communication expenses, and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our general and administrative expenses will increase due to many factors and the most significant of these factors include:

- increased personnel expenses to support the growth in research and development activities; and
- increased expenses related to becoming a publicly traded company, including increased legal and accounting services, addition of new headcount to support compliance and communication needs, and increased insurance premiums.

Other Income and Expense

Other income is comprised of interest income earned on cash, cash equivalents and available for sale securities, gain on the sale of available for sale securities, and a federal grant awarded to us under the Qualifying Therapeutic Discovery Project Program in 2010. Other expense includes interest expense associated with the convertible notes payable outstanding during 2011. In addition, we hold cash balances at financial institutions denominated in currencies other than the U.S. dollar to fund research and development activities performed by various third-party vendors. The translation of these currencies into U.S. dollars results in foreign currency gains or losses, depending on the change in value of these currencies against the U.S. dollar. These gains and losses are included in Other Income and Expense.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to vendors in connection with preclinical development activities;
- fees paid to vendors associated with the development of companion diagnostics; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. Based on the amount of accrued research and development expenses as of December 31, 2011, if our estimates of our net accrued liabilities are too high or too low by 5%, this could increase or decrease our research and development expenses by approximately $254,000.

Stock-Based Compensation

Described below is the methodology we have utilized in measuring stock-based compensation expense. Following the consummation of our initial public offering in November 2011, stock option values are determined based on the quoted market price of our common stock.

Since our inception in 2009, we applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, 718 “Accounting for Stock Based Compensation”, which we refer to as ASC 718. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. Compensation expense is recognized over the vesting period of the award. Calculating the fair value of stock-based awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the price volatility of our common stock, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Because we are a company with a limited operating history, we utilize data from several peer companies to estimate expected stock price volatility and the expected term of our options. We selected peer companies from the biopharmaceutical industry with similar characteristics as us, including stage of product development, market capitalization, number of employees and therapeutic focus. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

The fair value of stock options was estimated at the grant date using the following weighted average assumptions:

	Year Ended December 31, 2011	Year Ended December 31, 2010	Period from April 20, 2009 (Inception) Through December 31, 2009
Dividend yield	—	—	—
Volatility	74%	80%	80%
Risk-free interest rate	2.13%	2.10%	2.33%
Expected term (years)	6.0	5.6	5.3

In accordance with ASC 718, we recognized stock-based compensation expense of approximately $4,000, $68,000, and $1.3 million for the period April 20, 2009 (inception) through December 31, 2009 and for the years ended December 31, 2010 and 2011, respectively. As of December 31, 2011, we had $6.0 million in total unrecognized compensation expense, net of related forfeiture estimates, which is expected to be recognized over a weighted-average remaining vesting period of approximately 3.1 years. We expect our stock-based compensation to grow in future periods due to the potential increases in the value of our common stock and headcount.

Under ASC 718, we are required to estimate the level of forfeitures expected to occur and record compensation expense only for those awards that we ultimately expect will vest. Due to the lack of historical forfeiture activity of our plan, we estimated our forfeiture rate based on peer company data with characteristics similar to our company.

As there was no public market for our common stock until our initial public offering in November 2011, the estimated fair value of our common stock from April 2009 through the initial public offering date effective November 15, 2011 was determined contemporaneously by our board of directors based on valuation estimates provided by management and prepared in accordance with the framework of the 2004 AICPA Technical Practice Aid, Valuation of Privately-Held-Company Equity Practice Aids, or the Practice Aid.

For the period from April 20, 2009 (inception) to December 31, 2009, our board of directors determined the fair value of our common stock to be $0.29 per share. Due to the minimal value of non-cash assets owned during this period, the superior preferences associated with our convertible preferred stock in relation to our common stock and our focus on start up activities, there was a nominal value attributed to the fair value of our common stock during this time.

In the fourth quarter of 2009, we completed the in-licensing of our first product candidate and the issuance of our Series A-2 and Series B convertible preferred stock for total net proceeds of $65.6 million. Based on the significance of these transactions, we deemed it appropriate to update the estimated valuation of our common stock as of December 31, 2009. This valuation was updated again as of December 31, 2010.

Based on the valuation methodology selection criteria set forth in the Practice Aid and the stage of our development as a company as of December 31, 2009 and 2010, we determined that the Option Pricing Method based on a Black-Scholes option pricing model was the most appropriate valuation methodology to estimate the fair value of our common stock. We concluded that there were no significant transactions affecting our capital structure or changes in the development plans for our product candidates from what was previously expected which would have indicated that an update to our valuation was required at dates other than December 31, 2009 and 2010, which was validated by the relatively insignificant change in value during each period.

Key variables used in applying the Option Pricing Method are as follows:

- Underlying equity value — To estimate the value of our total equity (including both common and preferred equity), we utilized the marketable equity value based on the most recent rounds our preferred stock issuances, which we believed to be the most indicative of our value.
- Volatility — We estimated volatility based on comparison to volatility of publicly-traded comparable companies.
- Time to liquidity — We estimated time to a liquidity event based on the forecasted time to significant clinical development events for our product candidates which we believed could lead to an initial public offering, or IPO, or other type of liquidation event for our stockholders.
- Risk-free interest rate — We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a liquidation event for our stockholders.
- Discounts for lack of marketability — Because we are a privately-held company, shares of our common stock are highly illiquid and, as such, warrant a discount in value from their estimated "marketable" price. We estimate the discount factor for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately-held business valuations, fundamental business factors, and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black-Scholes option pricing model.

The following tables summarize the significant assumptions utilized in the Option Pricing Method used to determine the fair value of our common stock as of the dates indicated.

	December 31,		
	2009	2010	
		1 Yr. Liquidity	2 Yr. Liquidity
Underlying equity value ($ millions)	$ 89.7	$ 99.0	$ 104.4
Volatility	80%	70%	70%
Time to liquidity	3 yrs.	1 yr.	2 yrs.
Risk-free interest rate	1.69%	0.29%	0.61%
Discount for lack of marketability	5 5%	40%	50%
Estimated per-share fair value of common stock	$ 3.08	$ 3.10	$ 3.45
Average of 2010 valuations		$ 3.28	

For our valuation as of December 31, 2009, we assumed a three-year time to liquidity based on our assumption that clinical data from the LEAP study for CO-101 would be available in the fourth quarter of 2012. At that time, we believed that an IPO or other liquidity event would most likely occur following the availability of those data. For our valuation as of December 31, 2010, we performed two valuation models, one that assumed a one-year time to liquidity and another that assumed a two-year time to liquidity. As of December 31, 2010, we believed that a liquidity event was possible within one year due to the fact that we had in-licensed a second product candidate (CO-1686), which was expected to commence human clinical trials in the first half of 2012, and the development of CO-101 was progressing as planned. We also believed that a liquidity event was equally likely to occur after the availability of the clinical data from the LEAP study, which was still expected within two years of the valuation. Since neither of these scenarios seemed more likely than the other, we calculated valuations using both liquidity event assumptions and equally weighted the results to estimate the fair value of our common stock. The primary reason for the lower marketable value per share of our common stock in comparison to the marketable value per share of our preferred stock on each valuation date was the value of the superior rights and preferences associated with the preferred stock, the most significant of which are the liquidation rights held by the preferred stockholders.

The estimated fair value of our common stock increased significantly from our initial estimate of $0.29 made at our inception to $3.08 as of December 31, 2009. This increase was primarily due to our improved financial position resulting from the issuance of our Series A-2 and Series B convertible preferred stock as well as the in-licensing of our first product candidate, CO-101, each of which occurred in the fourth quarter of 2009. These events increased the likelihood of creating value for common stockholders above the thresholds necessary to satisfy the liquidation preferences held by our preferred stockholders.

In April 2011, our board of directors authorized management to pursue an IPO. As a result of this action, we determined that the valuation of our common stock should be updated to reflect the greater clarity as to a likely liquidity event for common stockholders (*i.e.*, the IPO), as well as the in-licensing of our third product candidate, rucaparib, and the issuance in May and June 2011 of $35.0 million in aggregate principal amount of our 5% convertible promissory notes due 2012. In accordance with the Practice Aid, we determined that the probability weighted expected return method, or PWERM, was the most appropriate valuation methodology going forward. Accordingly, we updated the valuation of our common stock effective June 30, 2011.

In our application of PWERM, we estimated the fair value of our common stock using three potential liquidity scenarios and then probability weighted the resulting valuation under each of these scenarios. The three liquidity scenarios assumed were as follows:

- completing the IPO, or the IPO scenario;
- remaining as a private company and selling the company at a future date, or the merger and acquisition, or M&A, scenario; and
- remaining as a private company and executing an IPO at a future date, or the Future IPO scenario.

In order to estimate our equity value under the IPO scenario, we employed an income approach using a discounted cash flow analysis. Net cash flows from the multi-year forecast for each of our product candidates were discounted to their present value based on our estimated weighted average cost of capital, or WACC. The WACC was estimated using a capital asset pricing model, taking into account risk-free interest rates, an equity risk premium, risk premiums for our industry and entity size, company-specific risks associated with the development and commercialization of our product candidates, and the cost and capital structure weighting of our debt. The estimated future cash flows were based on anticipated timing of the clinical development and regulatory approvals for each of our product candidates as well as their commercialization opportunity. This equity value was applied to the number of common shares outstanding determined on a fully diluted basis to calculate the per share fair value of our common stock, assuming the conversion of all preferred stock into common stock.

To value our common stock under the M&A and Future IPO scenarios, we utilized the Option Pricing Method as described above. However, for these scenarios the current value of our underlying common and preferred equity was determined using a discounted cash flow analysis that is substantially the same as the analysis performed for the IPO scenario rather than using a marketable equity value based on recent rounds of our preferred stock issuances as was used in the December 31, 2009 and 2010 valuations. We believed this to be a more accurate measurement of our equity value as of June 30, 2011 due to the 19 month time gap since our last issuance of preferred stock. Once our equity value for the M&A and Future IPO scenarios was determined, we allocated a portion of the value to our common stock based on a “best economic outcome” model. For the M&A scenario, the value assigned to our common stock was determined using a break point analysis to estimate the various enterprise values at which holders of each series of our preferred stock would elect to convert to common stock and the points at which holders of options would exercise as a result of the value of the common stock exceeding the exercise price. For the Future IPO scenario, the value assigned to our common stock was estimated using a fully diluted outstanding share analysis assuming the conversion of all preferred stock into common stock as such a conversion would be required to execute an IPO.

The following tables summarize the significant assumptions utilized for each of the valuation scenarios used to determine the fair value of our common stock as of June 30, 2011.

		Liquidity Scenario		
Key Assumptions		**Initial Public Offering**	**Future IPO**	**M&A**
Probability weighting		80%	10%	10%
Liquidity date		10/1/2011	6/30/2014	6/30/2014
Underlying equity value ($ millions)		$ 124.6	$ 120.0	$ 120.0
WACC		28%	N/A	N/A
Volatility		N/A	100%	100%
Risk-free interest rate		N/A	0.81%	0.81%
Discount for lack of marketability		N/A	50%	50%
Estimated per-share fair value of common stock		$ 12.47	$ 5.57	$ 4.93
PWERM	$11.02			

The estimated per share fair value of our common stock determined as of June 30, 2011 increased significantly from the December 31, 2010 valuation. This is primarily due to the April 2011 decision by our board of directors to authorize management to pursue an IPO and the June 2011 authorization of our board of directors to file a registration statement with the SEC, which, among other things, contributed to the elimination of the discount for lack of marketability from the IPO scenario in the June 30, 2011 analysis. Given the assumed acceleration of the IPO to October 1, 2011, we believe the value of our common stock no longer warrants a discount from its “marketable” price. In addition, the June 30, 2011 valuation was positively impacted by the assumption that all preferred stock would automatically convert into common stock upon the IPO, thereby eliminating the impact of preferred stock liquidation preferences on the value of the common stock.

We utilized the common stock valuation contemporaneously prepared as of December 31, 2010 to set the exercise price for stock options granted during the six months ended June 30, 2011. In light of the close proximity of the stock option grants in March, April, May and June 2011 to the April and June 2011 actions by our board of directors with respect to the IPO and our June 2011 entry into a license agreement to acquire exclusive global development and commercialization rights to rucaparib, we retrospectively determined to use the fair value of our common stock as of June 30, 2011 to calculate stock-based compensation expense for those stock option grants. No stock options were granted in January or February 2011.

The following table presents the grant dates and related exercise prices of stock options granted to our employees and our board of directors from April 20, 2009 (inception) through November 15, 2011, prior to the closing of our initial public offering, along with the corresponding exercise price for each grant and the fair value per share utilized to calculate stock-based compensation expense.

Month of Grant	Number of Shares Underlying Options Granted	Exercise Price per Share	Common Stock Fair Value per Share on Grant Date
August 2009	260,348	$ 0.29	$ 0.29
October 2009	34,482	$ 0.29	$ 0.29
November 2009	12,069	$ 0.29	$ 0.29
December 2009	4,311	$ 0.29	$ 0.29
April 2010	114,309	$ 3.08	$ 3.08
May 2010	29,309	$ 3.08	$ 3.08
June 2010	12,069	$ 3.08	$ 3.08
August 2010	1,034	$ 3.08	$ 3.08
October 2010	4,310	$ 3.08	$ 3.08
November 2010	31,897	$ 3.08	$ 3.08
December 2010	48,273	$ 3.08	$ 3.08
March 2011	534,449	$ 3.28	$ 11.02
April 2011	5,173	$ 3.28	$ 11.02
May 2011	12,412	$ 3.28	$ 11.02
June 2011	48,274	$ 3.28	$ 11.02
July 2011	5,172	$11.02	$ 11.02
August 2011	194,647	$11.02	$ 11.02
October 2011	18,016	$11.02	$ 11.02
November 2011	14,000	$11.02	$ 11.02

The price of our common stock at our initial public offering was $13.00 per share, as compared to our most recent common stock valuation of $11.02 per share completed as of June 30, 2011. We believe that the difference in estimated value between the IPO price and management's determination of the estimated fair value of our common stock as of June 30, 2011 is primarily the result of the contemporaneous valuation prepared as of June 30, 2011 containing multiple liquidity scenarios, including an initial public offering with an anticipated completion date of October 1, 2011 and two scenarios that assumed we remained as a private company for an extended period of time. If we had considered only the October 1, 2011 initial public offering scenario with 100% probability, the contemporaneous valuation would have resulted in a fair value determination of $12.47 per share, representing a discount of 4% from the IPO price.

There are significant judgments and estimates inherent in the determination of these valuations. These judgments and estimates include assumptions regarding our future performance, including the successful completion of our clinical trials as well as the determination of the appropriate valuation methods. If we had made different assumptions, our share-based compensation expense could have been different.

Results of Operations

Comparison of Years Ended December 31, 2011 and 2010 and the Period from April 20, 2009 (inception) to December 31, 2009:

Research and Development Expenses. Research and development expenses for the years ended December 31, 2011 and 2010 and the period from April 20, 2009 (inception) to December 31, 2009 were as follows:

	Years Ended		Period from April 20, 2009 (Inception) to December 31,
	2011	2010	2009
	(in thousands)		
Research and development expenses	$40,726	$ 22,323	$ 1,762
Increase from prior year	$ 18,403	$20,561	$ —
% Change from prior year	82.4%	1166.9%	—

The increase in research and development expenses for the year ended December 31, 2011 over 2010 was due primarily to development expenses associated with CO-101 and rucaparib clinical trials. Clinical trial expenses increased by $9.6 million due to growth in the number of patients, active sites and investigators that are participating in our CO-101 clinical trials and costs incurred for the development of companion diagnostics for our CO-101 drug product, as well as the assumption of clinical development costs for rucaparib following the in-licensing of that product candidate in June 2011. Drug product development and manufacturing activities also increased by $470,000 in support of the CO-101 development. In addition, $3.8 million of the increase was the result of discovery, formulation development, manufacturing, and the commencement of preclinical activities associated with CO-1686, a compound that was in-licensed in May 2010. The remaining increase of $4.5 million was due primarily to an increase in salaries, benefits and personnel related costs resulting from additional headcount hired to support the expanding development activities of CO-101, CO-1686 and rucaparib.

The increase in research and development expenses for the year ended December 31, 2010 over the period from April 20, 2009 (inception) to December 31, 2009 was due primarily to the commencement of research and development activities in 2010 for our in-licensed compounds CO-101 and CO-1686. Significant 2010 development activities included:

- increase of $5.5 million related to the commencement of our pivotal clinical trial for CO-101 in January 2010;
- increase of $4.7 million for CO-101 drug product development, clinical supply manufacturing and distribution;
- increase of $2.3 million associated with CO-1686 product development and IND enabling activities;
- increase of $2.0 million for the initiation of additional supporting CO-101 clinical studies;
- increase of $1.1 million for companion diagnostic development related to both CO-101 and CO-1686; and
- increase of $4.0 million to salaries, benefits and other personnel costs to support the growth in our 2010 development activities.

General and Administrative Expenses. General and administrative expenses for the years ended December 31, 2011 and 2010 and the period from April 20, 2009 (inception) to December 31, 2009 were as follows:

	Years Ended		Period from April 20, 2009 (Inception) to December 31,
	2011	2010	2009
	(in thousands)		
General and administrative expenses	$6,860	$4,302	$ 2,209
Increase from prior year	$2,558	$2,093	$ —
% Change from prior year	59.5%	94.7%	—

The increase in general and administrative expenses for the year ended December 31, 2011 over 2010 was primarily attributable to a full year's lease expense in 2011 associated with office space in San Francisco, California and Cambridge, England where the leases commenced in May 2010 and August 2010, respectively, as well as legal fees associated with patent review and analysis activities for two of our product candidates, and increased personnel, travel and information system costs to support company growth. Additionally, stock compensation expense increased by $701,000 relative to the increase in the valuation of our common stock in 2011.

The increase in general and administrative expenses for the year ended December 31, 2010 over the period from April 20, 2009 (inception) to December 31, 2009 was due primarily to an increase of $0.9 million in personnel related expenses to support corporate operational activities and the commencement of research and development activities for CO-101 and CO-1686 in 2010. In addition, office lease expense increased by $0.9 million due to new lease agreements for the Boulder, Colorado and San Francisco, California locations, effective in December 2009 and May 2010, respectively. In addition, we commenced operations in May 2009 and, as such, expenses for the period ended December 31, 2009 reflect only a partial year's activity.

Acquired In-Process Research and Development Expenses. Acquired in-process research and development expenses for the years ended December 31, 2011 and 2010 and the period from April 20, 2009 (inception) to December 31, 2009 were as follows:

	Years Ended		Period from April 20, 2009 (Inception) to December 31,
	2011	2010	2009
	(in thousands)		
Acquired in-process research and development	$ 7,000	$12,000	$ 13,085
Decrease from prior year	$(5,000)	$(1,085)	$ —
% Change from prior year	-41.7%	-8.3%	—

The decrease in acquired in-process research and development expenses for the year ended December 31, 2011 over 2010 was due to the difference in up-front acquisition costs for the development and commercialization rights of rucaparib in comparison to CO-1686 and CO-101. The licensing rights to rucaparib were acquired in June 2011. We made an up-front payment by issuing Pfizer a $7.0 million convertible promissory note, which was recognized as acquired in-process research and development expense. In May 2010, we acquired the global rights to develop and commercialize CO-1686 and made a $2.0 million up-front payment which was recognized as acquired in-process research and development expense. Additionally, in November 2010, we made a payment of $10.0 million to Clavis to expand the territory rights under the license agreement to include Asia and other international markets and we recorded this payment as acquired in-process research and development expense.

The decrease in acquired in-process research and development expenses for the year ended December 31, 2010 over the period from April 20, 2009 (inception) to December 31, 2009 was primarily due to the payments made for CO-101 licensing in 2010 vs. 2009 and the up-front acquisition costs for the worldwide rights to CO-1686. The rights to develop and commercialize CO-101 in North America, Central America, South America and Europe were licensed from Clavis in November 2009. As part of the in-license transaction, we recognized $13.1 million in 2009 as acquired in-process research and development expense. In November 2010, we made a payment of $10.0 million to Clavis to expand the territory rights under the license agreement to include Asia and other international markets and we recorded this payment as acquired in-process research and development expense. The acquired in-process research and development expense associated with CO-101 decreased $3.1 million for the year ended December 31, 2010 in comparison to the period from April 20, 2009 (inception) to December 31, 2009 as a result of the transactions described above. This reduction was partially offset by the acquisition of the worldwide rights to CO-1686 in May 2010. We recognized the up-front payment of $2.0 million for CO-1686 rights as acquired in-process research and development expense during 2010.

Other Income (Expense), Net. Other income (expense), net for the years ended December 31, 2011 and 2010 and the period from April 20, 2009 (inception) to December 31, 2009 were as follows:

	Years Ended		Period from April 20, 2009 (Inception) to December 31,
	2011	2010	2009
		(in thousands)	
Other income (expense), net:	$ (957)	$ 795	$ (43)
Increase (decrease) from prior year	$(1,752)	$ 838	$ —
% Change from prior year	-220.4%	1948.8%	—

The decrease in other income (expense), net for the year ended December 31, 2011 over 2010 was due to interest expense increasing by $851,000, resulting from the convertible promissory notes issued to our existing investors and Pfizer during the second quarter of 2011, which were subsequently converted to common stock upon the effective date of our initial public offering in November 2011. We also recorded $97,000 of debt issuance costs in 2011 associated with the issuance of convertible promissory notes. In addition, other expense increased in 2011 due to a $489,000 award received in 2010 under the Qualifying Therapeutic Discovery Project Program that did not occur in 2011, as well as a $183,000 reduction in foreign currency transaction gains in 2011 due primarily to a change in the value of the Euro in relation to the U.S. Dollar.

The increase in other income (expense), net for the year ended December 31, 2010 over the period from April 20, 2009 (inception) to December 31, 2009 was primarily due to a $489,000 award received in 2010 under the Qualifying Therapeutic Discovery Project Program for the development of CO-101 and CO-1686. In addition, $232,000 was due to the strengthening of the Euro value in relation to the U.S. Dollar over the 2010 year, which created an exchange gain to our Euro denominated cash account. The Euro cash account was established in May 2010 and had no impact in the period ended December 31, 2009.

Liquidity and Capital Resources

We have funded our operations primarily through the private placement of equity, convertible debt securities and our initial public offering completed in November 2011. As of December 31, 2011, we have received $75.5 million in net proceeds from the issuance of convertible preferred stock and $129.4 million in net proceeds from the issuance of common stock through our initial public offering. In May and June 2011, we received proceeds of $28.0 million through the issuance of convertible promissory notes. The outstanding principal amount and all accrued and unpaid interest converted into shares of our common stock immediately prior to the closing of our initial public offering at $13.00 per share, equal to our initial public offering price. As of December 31, 2011, we had cash, cash equivalents and available for sale securities totaling $140.2 million.

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Year Ended December 31, 2011	Year Ended December 31, 2010	Period from April 20, 2009 (Inception) to December 31, 2009
Net cash used in operating activities	$ (39,828)	$ (34,011)	$ (17,955)
Net cash provided by (used in) investing activities	9,168	(12,821)	(270)
Net cash provided by financing activities	158,346	29	75,536
Effect of exchange rate changes on cash and cash equivalents	42	—	—
Net increase (decrease) in cash and cash equivalents	$127,728	$ (46,803)	$ 57,311

Operating Activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The increase of $5.8 million to cash used in operating activities for the year ended December 31, 2011 in comparison to the prior year was due to an increase in clinical trial costs for CO-101 resulting from an increase in the number of patients enrolled and sites activated for our ongoing LEAP trial, commencement of CO-1686 research and development activities, in-licensed by us in May 2010, and commencement of product development and clinical trial activities for rucaparib, in-licensed by us in June 2011. The significant increase in cash used in operating activities for the year ended December 31, 2010 compared to the period from April 20, 2009 (inception) to December 31, 2009 was due to an increase in research and development expenses as we commenced development work on CO-101 and CO-1686 following the in-licensing of those programs in November 2009 and May 2010, respectively. In addition, we commenced operations in May 2009 and, as such, the period ended December 31, 2009 reflects only a partial year of activity.

Investing Activities

The cash provided by (used in) investing activities for all periods primarily reflects the purchase of available for sale securities offset by maturities and sales of available for sale securities. The increase of $22.0 million in cash provided by investing activities for the year ended December 31, 2011 compared to the year ended December 31, 2010 was due primarily to the maturities and sale of available for sale securities in 2011 to fund operations. Increase related to the sale and maturities of available for sale securities is partially offset by the purchase of $0.5 million in property and equipment in 2011 compared to $0.8 million in 2010. The net use of cash for these activities increased from zero in 2009 to $12.0 million in 2010 as we invested a portion of the proceeds received from the sale of convertible preferred stock in November 2009 in available for sale securities. In addition, we purchased $0.8 million in property and equipment in 2010 compared to $0.3 million in 2009.

Financing Activities

Cash provided by financing activities for the year ended December 31, 2011 was due to the issuance of $28.0 million of 5% convertible promissory notes for cash in the second quarter of 2011, the receipt of $129.4 million in net cash proceeds in the fourth quarter of 2011 from the sale of common stock during our initial public offering, and the exercise of stock options for $1.1 million. The cash provided by financing activities in 2009 was the result of the sale and issuance of 5,044,828 shares of our Series A-1 convertible preferred stock for net proceeds of $9.9 million, 5,044,828 shares of our Series A-2 convertible preferred stock for net proceeds of $15.1 million, and 10,919,540 shares of our Series B convertible preferred stock for net proceeds of $50.4 million.

Operating Capital Requirements

Assuming we successfully complete clinical trials and obtain requisite regulatory approvals, we do not anticipate commercializing any of our product candidates until 2014 at the earliest. As such, we anticipate that we will continue to generate significant losses for the next several years as we incur expenses to complete our development activities for each of our programs, including clinical trial activities, companion diagnostic development, drug development, establishing our commercial capabilities, and expanding our general and administrative functions to support the growth in our research and development and commercial organizations.

The net proceeds from our initial public offering will not be sufficient to fund our operations through successful development and commercialization of our product candidates. As a result, we will need to raise additional capital following our initial public offering to fund our operations and continue to conduct clinical trials to support additional development and potential regulatory approval, make milestone payments to our licensors and commercialize our product candidates.

We believe that our existing cash and cash equivalents and available for sale securities, will allow us to fund our operating plan through at least the next 12 months. If our available cash and cash equivalents and available for sale securities are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our shareholders.

In addition, if we raise additional funds through the issuance of debt securities or convertible preferred stock, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations. Furthermore, any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of our planned development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of the product candidates, companion diagnostics, and indications we pursue;
- the achievement of various development, regulatory and commercial milestones resulting in required payments to partners pursuant to the terms of our license agreements;
- the scope, progress, results and costs of researching and developing our product candidates and related companion diagnostics and conducting clinical and preclinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates and companion diagnostics;
- the cost of commercialization activities, if any, of our product candidates are approved for sale, including marketing and distribution costs;
- the cost of manufacturing any of our product candidates we successfully commercialize;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and outcome of such litigation; and
- the timing, receipt and amount of sales, if any, of our product candidates.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2011 (in thousands):

	Payments due by Period				
Contractual Obligations	**Total**	**Less than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More than 5 Years**
Operating lease obligations	$1,533	$ 751	$ 592	$ 190	$ —

In addition, we have certain obligations under licensing agreements with third parties contingent upon achieving various development, regulatory and commercial milestones. Pursuant to our license agreement with Clavis for the development and commercialization of CO-101, we may be required to pay Clavis an aggregate of up to $115.0 million if certain clinical study objectives and regulatory filings and approvals are achieved. Further, we may be required to pay Clavis up to an aggregate of $445.0 million in sales milestone payments if certain annual sales targets are met for CO-101. Subject to certain conditions set forth in the license agreement, Clavis may elect to co-develop and co-promote CO-101 in Europe. If Clavis were to make this election, it would be required to reimburse us for a portion of both past and future development costs. In addition, the milestone payments described above would be reduced. Pursuant to our license agreement with Avila for the development and commercialization of CO-1686, we may be required to pay Avila an aggregate of up to $119.0 million if certain clinical study objectives and regulatory approvals are achieved, of which we have already paid $4.0 million in the first quarter of 2012 upon filing the IND for CO-1686. Further, we may be required to pay Avila an aggregate of up to $120.0 million in sales milestone payments if certain annual sales targets are met for CO-1686. Pursuant to our license agreement with Pfizer for the development of rucaparib, which was signed in June 2011, we may be required to pay Pfizer up to an aggregate $259.0 million in milestone payments upon the successful attainment of development, regulatory and sales milestones. Finally, pursuant to terms of each of these license agreements, we will pay royalties to our licensors on sales, if any, of the respective products.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the rules promulgated by the SEC.

Tax Loss Carryforwards

As of December 31, 2011, we have federal net operating loss carryforwards of approximately $63.6 million to offset future federal income taxes. We also have federal research and development tax credit carryforwards of $18.2 million to offset future federal income taxes. The federal net operating loss carryforwards and research and development tax credit carryforwards expire at various times through 2031. To date, there have not been any ownership changes under Section 382 of the Code that would limit the amount of net operating loss carryforwards and tax credit carryfowards available in future years. However, the occurrence of certain events, including significant changes in ownership interests, may limit the amount of the tax carryforwards available in future years. At December 31, 2011, we recorded a 100% valuation allowance against our net operating loss and research and development tax credit carryforwards of approximately $44.3 million, as we believe it is more likely than not that the tax benefits will not be fully realized. In the future, if we determine that a portion or all of the tax benefits associated with our tax carryforwards will be realized, net income would increase in the period of determination.

Recently Adopted Accounting Standards

In June 2011, the FASB issued Accounting Standards Update No. 2011-05, Presentation of Comprehensive Income. This update eliminates the current option to report other comprehensive income and its components in the statement of shareholders' equity. This update is intended to enhance comparability between entities that report under GAAP and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. This standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We do not expect the adoption of this update to cause any material changes to the disclosures in, or the presentation of, our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2011, we had cash, cash equivalents and available for sale securities of $140.2 million, consisting of money market funds and U.S. government and agency obligations. The primary objectives of our investment policy are to preserve principal and maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We contract with CROs, investigational sites, and contract manufacturers globally. We may be subject to fluctuations in foreign currency rates in connection with these agreements. While we periodically hold foreign currencies, primarily Euro and Pound Sterling, we do not use other financial instruments to hedge our foreign exchange risk. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of December 31, 2011 and December 31, 2010, approximately 31% and 23%, respectively, of our total liabilities were denominated in currencies other than the functional currency.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included in Item 15 of this report and are presented beginning on page F-1.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2011, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2011, the design and operation of our disclosure controls and procedures were effective.

Management's Report on and Changes in Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to the transition period established by rules of the SEC for newly public companies.

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2012 annual meeting of stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, also referred to in this Form 10-K as our 2012 Proxy Statement, which we expect to file with the SEC no later than April 30, 2012.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information regarding our directors, including the audit committee and audit committee financial experts, and executive officers and compliance with Section 16(a) of the Exchange Act will be included in our 2012 Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Ethics for all of our directors, officers and employees as required by NASDAQ governance rules and as defined by applicable SEC rules. Stockholders may locate a copy of our Code of Business Ethics on our website at *www.clovisoncology.com* or request a copy without charge from:

Clovis Oncology, Inc.
Attention: Investor Relations
2525 28th Street, Suite 100
Boulder, CO 80301

We will post to our website any amendments to the Code of Business Ethics, and any waivers that are required to be disclosed by the rules of either the SEC or NASDAQ.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation will be included in our 2012 Proxy Statement and is incorporated herein by reference.

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

The information required by this item regarding security ownership of certain beneficial owners and management will be included in the 2012 Proxy Statement and is incorporated herein by reference.

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

The information required by this item regarding certain relationships and related transactions and director independence will be included in the 2012 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item regarding principal accounting fees and services will be included in the 2012 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are being filed as part of this report:

(1) Financial Statements.

Reference is made to the Index to Financial Statements of Clovis Oncology, Inc. appearing on page F-1 of this report.

(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Financial Statements or the Notes thereto.

(3) Exhibits.

Reference is made to the Index to Exhibits filed as a part of this Annual Report on Form 10-K.

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.

CLOVIS ONCOLOGY, INC.

By: /S/ PATRICK J. MAHAFFY
Patrick J. Mahaffy
President and Chief Executive Officer

Date: March 14, 2012

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

Name	Title	Date
/S/ PATRICK J. MAHAFFY **Patrick J. Mahaffy**	President and Chief Executive Officer; Director *(Principal Executive Officer)*	March 14, 2012
/S/ ERLE T. MAST **Erle T. Mast**	Executive Vice President and Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 14, 2012
/S/ BRIAN G. ATWOOD **Brian G. Atwood**	Director	March 14, 2012
/S/ M. JAMES BARRETT **M. James Barrett**	Director	March 14, 2012
/S/ JAMES C. BLAIR **James C. Blair**	Director	March 14, 2012
/S/ PAUL KLINGENSTEIN **Paul Klingenstein**	Director	March 14, 2012
/S/ EDWARD J. MCKINLEY **Edward J. McKinley**	Director	March 14, 2012
/S/ JOHN C. REED **John C. Reed**	Director	March 14, 2012
/S/ THORLEF SPICKSCHEN **Thorlef Spickshen**	Director	March 14, 2012

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors
Clovis Oncology, Inc.

We have audited the accompanying consolidated balance sheets of Clovis Oncology, Inc. (the Company), a corporation in the development stage, as of December 31, 2011 and 2010, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years ended December 31, 2011 and 2010 and for the periods from April 20, 2009 (Inception) to December 31, 2009 and 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes 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. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the years ended December 31, 2011 and 2010 and for the periods from April 20, 2009 (Inception) to December 31, 2009 and 2011, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Denver, Colorado
March 14, 2012

CLOVIS ONCOLOGY, INC
(A Development Stage Enterprise)

Consolidated Statements of Operations

	For the Year Ended December 31, 2011	For the Year Ended December 31, 2010	Period from April 20, 2009 (Inception) to December 31, 2009	Cumulative from April 20, 2009 (Inception) to December 31, 2011
	(in thousands, except per share amounts)			
Revenues	$ —	$ —	$ —	$ —
Operating Expenses:				
Research and development	40,726	22,323	1,762	64,811
General and administrative	6,860	4,302	2,209	13,371
Acquired in-process research and development	7,000	12,000	13,085	32,085
Operating loss	(54,586)	(38,625)	(17,056)	(110,267)
Other income (expense), net	(957)	795	(43)	(205)
Loss before income taxes	(55,543)	(37,830)	(17,099)	(110,472)
Income taxes	(27)	—	—	(27)
Net loss	$(55,570)	$ (37,830)	$ (17,099)	$(110,499)
Basic and diluted net loss per common share	$ (14.42)	$ (28.55)	$ (15.38)	$ (51.06)
Basic and diluted weighted average common shares outstanding	3,854	1,325	1,112	2,164

See accompanying notes.

CLOVIS ONCOLOGY, INC
(A Development Stage Enterprise)

Consolidated Balance Sheets

	December 31, 2011	December 31, 2010
	(in thousands, except for share amounts)	
Assets		
Current assets:		
Cash and cash equivalents	$ 138,236	$ 10,508
Available for sale securities	2,012	11,791
Prepaid research and development expenses	1,020	1,826
Other current assets	247	1,096
Total current assets	141,515	25,221
Property and equipment, net	1,896	951
Other assets	34	28
Total assets	$ 143,445	$ 26,200
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,036	$ 1,400
Accrued research and development expenses	5,071	3,195
Other accrued expenses	2,889	740
Total current liabilities	10,996	5,335
Non-current liabilities	656	115
Commitments and contingencies (Note 9)		
Convertible preferred stock, $0.001 par value per share, no shares and 36,296,552 shares authorized at December 31, 2011 and 2010, respectively;		
Series A-1 convertible preferred stock; no shares and 5,044,828 shares authorized, issued and outstanding at December 31, 2011 and 2010, respectively	—	9,916
Series A-2 convertible preferred stock; no shares and 5,044,828 shares authorized, issued and outstanding at December 31, 2011 and 2010, respectively	—	15,135
Series B convertible preferred stock; no shares and 10,919,540 shares authorized, issued and outstanding at December 31, 2011 and 2010, respectively	—	50,448
Stockholders' equity (deficit):		
Preferred Stock, par value $0.001 per share; 10,000,000 shares and no shares authorized at December 31, 2011 and 2010, respectively; no shares issued and outstanding at December 31, 2011 and 2010, respectively		
Common stock, $0.001 par value per share, 100,000,000 and 55,000,000 shares authorized at December 31, 2011 and 2010, respectively; 22,375,757 and 1,337,076 shares issued and outstanding at December 31, 2011 and 2010, respectively	22	1
Additional paid-in capital	242,221	137
Accumulated other comprehensive income	49	42
Deficit accumulated during development stage	(110,499)	(54,929)
Total stockholders' equity (deficit)	131,793	(54,749)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 143,445	$ 26,200

See accompanying notes.

CLOVIS ONCOLOGY, INC
(A Development Stage Enterprise)

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Deficit Accumulated During Development Stage	Total Stockholders' Equity (Deficit)	Comprehensive Loss
	Shares	Amount	Shares	Amount					
					(in thousands, except for share amounts)				
Balance at April 20, 2009 (inception)	—	$ —	—	$ —	$ —	$ —	$ —	$ —	$ —
Issuance of common stock to founders at $.001 per share	—	—	1,206,899	1	2	—	—	3	
Issuance of convertible preferred stock; $2.00, $3.00 and $4.62 per share for series A-1, A-2 and B, respectively, net of issuance costs of $174	21,009,196	75,499	—	—	—	—	—	—	
Exercise of stock options	—	—	114,659	—	33	—	—	33	
Share-based compensation expense	—	—	—	—	4	—	—	4	
Net loss	—	—	—	—	—	—	(17,099)	(17,099)	(17,099)
Balance at December 31, 2009	21,009,196	75,499	1,321,558	1	39	—	(17,099)	(17,059)	(17,099)
Exercise of stock options	—	—	15,518	—	29	—	—	29	
Share-based compensation expense	—	—	—	—	68	—	—	68	
Net unrealized gain on available for sale securities	—	—	—	—	—	42	—	42	42
Net loss	—	—	—	—	—	—	(37,830)	(37,830)	(37,830)
Balance at December 31, 2010	21,009,196	75,499	1,337,076	1	136	42	(54,929)	(54,750)	(37,788)
Issuance of common stock, net of issuance costs of $9,745	—	—	10,700,000	11	129,344	—	—	129,355	
Exercise of stock options	—	—	336,370	—	76	—	—	76	
Share-based compensation expense	—	—	—	—	1,325	—	—	1,325	
Conversion of convertible promissory notes and accrued interest into common stock	—	—	2,757,788	3	35,848	—	—	35,851	
Conversion of convertible preferred stock into common stock	(21,009,196)	(75,499)	7,244,523	7	75,492			75,499	
Net unrealized loss on available for sale securities	—	—	—	—	—	(40)	—	(40)	(40)
Currency translation adjustment	—	—	—	—	—	47	—	47	47
Net loss	—	—	—	—	—	—	(55,570)	(55,570)	(55,570)
Balance at December 31, 2011	—	$ —	22,375,757	$ 22	$242,221	$ 49	$(110,499)	$ 131,793	$ (55,563)

See accompanying notes.

CLOVIS ONCOLOGY, INC
(A Development Stage Enterprise)

Consolidated Statements of Cash Flows

	Year Ended December 31,		Period from April 20, 2009 (Inception) to December 31, 2009	Cumulative from April 20, 2009 (Inception) to December 31, 2011
	2011	2010		
	(in thousands)			
Operating activities				
Net loss	$ (55,570)	$ (37,830)	$ (17,099)	$(110,499)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	185	83	6	274
Share-based compensation expense	1,325	68	4	1,397
Amortization of premiums and discounts on available for sale securities	141	320	—	461
Gain on sale of available for sale securities	(16)	(18)	—	(34)
Non-cash acquired in-process research and development	7,000	—	—	7,000
Changes in operating assets and liabilities:				
Prepaid and accrued research and development expenses	2,682	2,896	(1,527)	4,051
Other operating assets	924	(1,040)	(84)	(200)
Accounts payable	1,656	866	534	3,056
Other accrued expenses	1,845	644	211	2,700
Net cash used in operating activities	(39,828)	(34,011)	(17,955)	(91,794)
Investing activities				
Purchases of property and equipment	(446)	(770)	(270)	(1,486)
Purchases of available for sale securities	—	(27,008)	—	(27,008)
Maturities and sales of available for sale securities	9,614	14,957	—	24,571
Net cash provided by (used in) investing activities	9,168	(12,821)	(270)	(3,923)
Financing activities				
Proceeds from sale of convertible preferred stock, net of issuance costs	—	—	75,499	75,499
Proceeds from sale of common stock, net of issuance costs	129,355	—	4	129,359
Proceeds from stock option exercises	1,089	29	33	1,151
Proceeds from issuance of convertible promissory notes, net of issuance costs	27,902	—	—	27,902
Net cash provided by financing activities	158,346	29	75,536	233,911
Effect of exchange rate changes on cash and cash equivalents	42	—	—	42
Increase (decrease) in cash and cash equivalents	127,728	(46,803)	57,311	138,236
Cash and cash equivalents at beginning of period	10,508	57,311	—	—
Cash and cash equivalents at end of period	$ 138,236	$ 10,508	$ 57,311	$ 138,236
Non-cash items:				
Conversion of convertible preferred stock to common stock	$ 75,499	$ —	$ —	$ 75,499
Conversion of convertible promissory notes and accrued interest to common stock	$ 35,851	—	—	$ 35,851
Assets recorded for which payment has not yet occurred	$ 684	—	—	$ 684

See accompanying notes.

1. Nature of Business

Clovis Oncology, Inc. (the "Company"), a corporation in the development stage, was incorporated in Delaware on April 20, 2009, and commenced operations in May 2009. The Company is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and other international markets. The Company has and intends to continue to license or acquire rights to oncology compounds in all stages of clinical development. In exchange for the right to develop and commercialize these compounds, the Company generally expects to provide the licensor with a combination of up-front payments, milestone payments and royalties on future sales. In addition, the Company generally expects to assume the responsibility for future drug development and commercialization costs. The Company currently operates in one segment. Since inception, the Company's operations have consisted primarily of developing three in-licensed compounds and their companion diagnostics, evaluating new product acquisition candidates, raising capital and corporate organization activities. The Company has never earned revenue from these activities, and accordingly, the Company is considered to be in the development stage as of December 31, 2011.

On September 22, 2011, the Board of Directors and stockholders of the Company effectuated a 1 for 2.9 reverse split of the Company's common stock. The historical financial statements and related notes have been retrospectively adjusted to give effect to this change.

In November 2011, the Company completed its initial public offering ("IPO"), which resulted in net proceeds of $129.4 million from the issuance of 10,700,000 shares of common stock, which includes the sale of 700,000 shares under the underwriters' over-allotment option . In connection with the initial public offering, all of the outstanding shares of the Company's convertible preferred stock and convertible promissory notes payable and related accrued interest were converted into 10,002,311 shares of common stock.

Liquidity

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through private equity financings and its initial public offering, and management expects operating losses and negative cash flows to continue for at least the next several years. As the Company continues to incur losses, transition to profitability is dependent upon the successful development, approval, and commercialization of its product candidates and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional cash. Management intends to fund future operations through additional private or public debt or equity offerings, and may seek additional capital through arrangements with strategic partners or from other sources. Based on the Company's operating plan, existing working capital at December 31, 2011 is sufficient to meet the cash requirements to fund planned operations through at least December 31, 2012 without additional sources of cash, although there can be no assurance that this can, in fact, be accomplished.

2. Summary of Significant Accounting Policies

Basis of Presentation

The information reported within the Company's financial statements from April 20, 2009 to December 31, 2010 was based solely on the accounts of Clovis Oncology, Inc. Effective January 1, 2011, Clovis Oncology UK Limited, a wholly owned subsidiary of the Company, commenced operations. All financial information presented after December 31, 2010 was consolidated and includes the accounts of the Company and its wholly owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation. The financial statements are prepared in conformity with U.S. generally accepted accounting principles ("GAAP"). Subsequent events have been evaluated through the date these financial statements were filed with the Securities & Exchange Commission.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, other comprehensive loss and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to clinical trial accruals and stock-based compensation expense. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Fair Value of Financial Instruments

Cash, cash equivalents and available for sale securities are carried at fair value (see Note 4). Financial instruments, including prepaid expenses, accounts payable and accrued liabilities, are carried at cost, which approximates fair value given their short-term nature.

Cash, Cash Equivalents and Available for Sale Securities

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificate of deposits, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

2. Summary of Significant Accounting Policies (Continued)

Marketable securities with original maturities greater than three months are considered to be available for sale securities and consist of U.S. agency obligations, U.S. government obligations and corporate debt obligations. Available for sale securities are reported at fair market value and unrealized gains and losses are included as a separate component of stockholders' equity (deficit). Realized gains, realized losses, the amortization of premiums and discounts, interest earned and dividends earned are included in other income (expense). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year are classified as short-term based on management's intent to fund current operations with these securities or to make them available for current operations. A decline in the market value of a security below its cost value that is deemed to be other than temporary is charged to earnings, and results in the establishment of a new cost basis for the security.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. Equipment purchased for use in manufacturing and clinical trials is evaluated to determine whether the equipment is solely beneficial for a drug candidate in the development stage or whether it has an alternative use. Equipment with an alternative use is capitalized. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Maintenance and repairs are expensed as incurred. The following estimated useful lives were used to depreciate the Company's assets:

	Estimated Useful Life
Computer hardware and software	3 years
Leasehold improvements	6 years
Laboratory, manufacturing and office equipment	7 years
Furniture and fixtures	10 years

Long-Lived Assets

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses have been recorded through December 31, 2011.

Other Accrued Expenses

Other accrued expenses are comprised of the following:

	December 31,	
	2011	2010
Accrued personnel costs	$ 2,373	$632
Accrued corporate legal fees and professional services	231	95
Accrued expenses – other	285	13
Other accrued expenses	$2,889	$ 740

2. Summary of Significant Accounting Policies (Continued)

Research and Development Expense

Research and development costs are charged to expense as incurred and include, but are not limited to, salary and benefits, clinical trial activities, drug development and manufacturing, and third-party service fees, including clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development.

Acquired In-Process Research and Development Expense

The Company has acquired and expects to continue to acquire the rights to develop and commercialize new drug candidates. The up-front payments to acquire a new drug compound, as well as future milestone payments, are immediately expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

Share-Based Compensation Expense

Share-based compensation is recognized as expense for all share-based awards made to employees and directors and is based on estimated fair values. The Company determines equity-based compensation at the grant date using the Black-Scholes option pricing model. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period. Any changes to the estimated forfeiture rates are accounted for prospectively.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and available for sale securities. The Company maintains its cash and cash equivalent balances in the form of money market accounts with financial institutions that management believes are creditworthy. Available for sale securities are invested in accordance with the Company's investment policy. The investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company has no financial instruments with off-balance-sheet risk of accounting loss.

Foreign Currency

The assets and liabilities of the Company's foreign operations are translated in U.S. dollars at current exchange rates and the results of operations are translated at the average exchange rates for the reported periods. The resulting translation adjustments are included in accumulated other comprehensive income on the consolidated balance sheets. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. Transaction gains and losses are recorded to other income (expense), net in the Consolidated Statements of Operations. As of December 31, 2011 and 2010, approximately 31% and 23% of the Company's total liabilities were denominated in currencies other than the functional currency, respectively.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized.

Recently Adopted and Issued Accounting Standards

In June 2011, the FASB issued Accounting Standards Update No. 2011-05, Presentation of Comprehensive Income. This update eliminates the current option to report other comprehensive income and its components in the statement of shareholders' equity. This update is intended to enhance comparability between entities that report under GAAP and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. This standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We do not expect the adoption of this update to cause any material changes to the disclosures in, or the presentation of, our consolidated financial statements.

3. Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2011	2010
Laboratory, manufacturing and office equipment	$ 1,170	$ 366
Furniture and fixtures	520	419
Computer hardware and software	340	116
Leasehold improvements	140	139
Total property and equipment	2,170	1,040
Less: accumulated depreciation	(274)	(89)
Property and equipment, net	$1,896	$ 951

Depreciation expense related to property and equipment was $185,000, $83,000, $6,000 and $274,000 for the years ended December 31, 2011 and 2010, respectively, and for the periods from April 20, 2009 (inception) to December 31, 2009 and 2011, respectively.

4. Fair Value Measurements

Fair value is defined as the exchange price that would be received to sell an asset or paid to transfer a liability (at 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. The three levels of inputs that may be used to measure fair value include:

Level 1: Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets and liabilities consist of money market investments.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company's Level 2 assets and liabilities include U.S. government obligations, U.S. government agency obligations and corporate debt securities.

Level 3: Unobservable inputs that are supported by little or no market activity. The Company does not have Level 3 assets or liabilities.

The following table identifies the Company's assets that were measured at fair value on a recurring basis (in thousands):

Description	Balance	Level 1	Level 2	Level 3
December 31, 2011				
Money market	$ 136,273	$136,273	$ —	$—
U.S. agency obligations	2,012	—	2,012	—
Corporate debt securities	—	—	—	—
U.S. government obligations	—	—	—	—
Total assets at fair value	$138,285	$136,273	$ 2,012	$—
December 31, 2010				
Money market	$ 7,010	$ 7,010	$ —	$—
U.S. agency obligations	4,109	—	4,109	—
Corporate debt securities	3,656	—	3,656	—
U.S. government obligations	4,026	—	4,026	—
Total assets at fair value	$ 18,801	$ 7,010	$11,791	$—

There were no security transfers between Levels 1 and 2 in 2011.

5. Available for Sale Securities

The Company's available for sale securities at cost or amortized cost value and fair market value by contractual maturity were (in thousands):

	Cost or Amortized Cost Value	Fair Market Value
December 31, 2011		
Due in one year or less	$ 2,010	$ 2,012
Due after one year through two years	—	—
Total	$ 2,010	$ 2,012
December 31, 2010		
Due in one year or less	$ 7,663	$ 7,675
Due after one year through two years	4,087	4,116
Total	$11,750	$11,791

The types of securities included in the Company's available for sale investments were (in thousands):

	Cost or Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Market Value
December 31, 2011				
U.S. government agencies	$ 2,010	$ 2	$ —	$ 2,012
December 31, 2010				
U.S. government agencies	$ 4,095	$ 14	$ —	$ 4,109
U.S. government obligations	4,002	24	—	4,026
Corporate debt securities	3,653	4	(1)	3,656
Total	$11,750	$ 42	$ (1)	$11,791

No securities have been in a continuous unrealized loss position for more than 12 months at December 31, 2011 and 2010, respectively, and no impairments have been recorded for the periods presented.

6. Convertible Promissory Notes

In May 2011, the Company issued $20.0 million of 5% Convertible Promissory Notes to existing investors for cash. In June 2011, the Company issued $15.0 million of 5% Convertible Promissory Notes to Pfizer, which was comprised of a $7.0 million note issued to acquire the global rights to develop and market rucaparib and an $8.0 million note issued for cash (the "Notes"). The Notes accrued interest at an annual rate of 5% and had a maturity date of May 25, 2012. In connection with the completion of the Company's initial public offering in November 2011, the principal balance and all accrued and unpaid interest due on the Notes was converted into 2,757,788 shares of the Company's common stock.

7. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Common Stock

In May 2009, the Company issued 1,206,899 shares of its common stock to the original founders at a purchase price of $.0029 per share. The shares were issued under restricted stock purchase agreements, which allow the Company, at its discretion, to repurchase unvested shares if the founders terminate their employment with the Company. In addition, if the founders employment is terminated by the Company without "cause" within six months following a change in control, 100% of the unvested shares of the restricted stock will immediately vest upon termination. Upon execution of the restricted stock purchase agreements, 25% of the shares vested immediately and the remaining shares vest ratably on a monthly basis over a four-year term. As of December 31, 2011 and 2010, 320,581 and 546,876 shares remained unvested, respectively.

In November 2011, the Company sold 10,700,000 shares of our common stock in an initial public offering at a price of $13.00 per share. The number of shares issued included 700,000 shares purchased by the underwriters pursuant to their partial exercise of their overallotment option. The Company received net proceeds from the offering of $129.4 million, after deduction of $6.9 million of underwriting commissions and $2.8 million of offering expenses.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company. Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Company's Board of Directors.

Preferred Stock

In May 2009, the Company entered into the Series A-1, A-2, B and C Preferred Stock Purchase Agreement with various investors (the "Preferred Stock Purchase Agreement"). The Preferred Stock Purchase Agreement provided for the issuance of up to $146.3 million of the Company's convertible preferred stock, subject to various terms and conditions. During 2009, the Company issued shares of Series A-1, Series A-2 and Series B convertible preferred stock resulting in total aggregate cash proceeds to the Company of $75.5 million, net of $174,000 related stock issuance costs.

7. Convertible Preferred Stock and Stockholders' Deficit (Continued)

In connection with the completion of the Company's initial public offering in November 2011, all of the outstanding shares of convertible preferred stock were automatically converted into 7,244,523 shares of the Company's common stock. Prior to the initial public offering, holders of the Series A-1, A-2 and B convertible preferred stock had the right to convert the convertible preferred stock, at any time, into shares of common stock. The Series A-1, A-2 and B convertible preferred stock was converted at a rate of 2.9 for 1 into common stock based upon the election of the convertible preferred stock holders immediately prior to the closing of the initial public offering. The preferred shares also contained beneficial liquidation and dividend preferences, none of which were realized due to the conversion of the shares into common stock immediately prior to the closing of the initial public offering.

8. Share-Based Compensation

Stock Options

In May 2009, the Company's Board of Directors approved the 2009 Equity Incentive Plan (the "2009 Plan"). The 2009 Plan provided for the granting of stock options and other stock-based awards, including restricted stock, stock appreciation rights and restricted stock units to its employees, directors and consultants. Common shares authorized for issuance under the 2009 Plan were 1,370,363 and 1,034,483 at December 31, 2011 and 2010, respectively. Options to purchase common stock under the 2009 Plan were designated as incentive stock options or non-statutory stock options. Stock options granted under this 2009 Plan vest over either a one-year period or three-year period for Board of Director grants and over a four-year period for employee grants and expire 10 years from the date of grant. Upon the closing of the initial public offering in November 2011, 138,258 shares remaining for future issuance under this 2009 Plan were transferred to the 2011 Equity Incentive Plan and no further grants will be made under this 2009 Plan. Forfeitures under the 2009 Plan will be available for grant under the 2011 Plan.

In August 2011, the Company's Board of Directors approved the 2011 Equity Incentive Plan (the "2011 Plan"), which became effective upon the closing of the Company's initial public offering in November 2011. The 2011 Plan provides for the granting of incentive and nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards and other stock-based awards to its employees, directors and consultants. Common shares authorized for issuance under the 2011 Plan were 1,388,258 at December 31, 2011, which represents the initial reserve of 1,250,000 shares of common stock plus 138,258 shares of common stock remaining for future issuance from the 2009 Equity Incentive Plan. Stock options granted to date vest over either a one-year period or three-year period for Board of Director grants or over a four-year period for employee grants and expire 10 years from the date of grant.

Stock-based compensation expense for the years ended December 31, 2011 and 2010, respectively, the period from April 20, 2009 to December 31, 2009, and the cumulative period from April 20, 2009 to December 31, 2011 has been recognized in the accompanying Statements of Operations as follows:

	Year Ended December 31,		Period from April 20, 2009 (Inception) to December 31, 2009	Cumulative Period from April 20, 2009 (Inception) to December 31, 2011
	2011	2010		
Research and development	$ 608	$ 52	$ —	$ 660
General and administrative	717	16	4	737
Total stock-based compensation expense	$ 1,325	$ 68	$ 4	$ 1,397

8. Share-Based Compensation (Continued)

The following table summarizes the activity relating to the Company's options to purchase common stock:

	Option Shares Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at April 20, 2009 (inception)	—	$ —		
Granted	311,210	0.29		
Exercised	(114,659)	0.29		
Balance at December 31, 2009	196,551	0.29	9.69	
Granted	241,201	3.08		
Exercised	(15,518)	1.84		
Balance at December 31, 2010	422,234	$ 1.83	9.14	$ 612,320
Granted	863,143	5.70		
Exercised	(336,370)	3.24		
Forfeited	(14,191)	3.08		
Balance at December 31, 2011	934,816	$ 4.88	8.93	$ 8,611,945
Vested and expected to vest at December 31, 2011	849,508	$ 4.70	8.89	$ 7,979,186
Vested at December 31, 2011	201,652	$ 1.22	7.99	$2,595,699

The aggregate intrinsic value in the tables above represents the pretax intrinsic value, based on our closing stock price of $14.09 as of December 31, 2011, and our closing valuation price of $3.08 as of December 31, 2010, which would have been received by the option holders had all option holders with in-the-money options exercised their options as of that date.

	Year Ended		Period from April 20, 2009 (Inception) to
	December 31, 2011	December 31, 2010	December 31, 2009
Weighted-average grant-date fair value per share	$ 8.62	$ 2.10	$ 0.20
Intrinsic value of options exercised	$ 505,806	$ 19,100	$ —
Cash received from stock option exercises	$1,088,737	$ 28,500	$ 33,250

The 2009 Plan allows for the option holder to exercise stock option shares prior to the vesting of the option. The shares acquired from an early exercise are subject to repurchase if the option holder terminates employment or service with the Company. The number of unvested common shares at the point of termination will be repurchased by the Company at the stated exercise price of the option. The number of common shares exercised prior to vesting was 354,367 and 86,461 at December 31, 2011 and December 31, 2010, respectively. The number of early exercised shares expected to vest using estimated forfeiture rates over the remaining service period of the option term was 300,346 and 71,807 at December 31, 2011 and December 31, 2010, respectively.

8. Share-Based Compensation (Continued)

The fair value of each stock-based award is estimated on the grant date using the Black-Scholes option pricing model using the weighted-average assumptions provided in the following table:

	Year Ended December 31,		
	2011	2010	2009
Risk-free interest rate(a)	2.13%	2.10%	2.33%
Dividend yield	—	—	—
Volatility(b)	74%	80%	80%
Expected term (years)(c)	6.0	5.6	5.3

(a) *Risk-free interest rate:* The rate is based on the yield on the grant date of a zero-coupon U.S. Treasury bond whose maturity period approximates the option's expected term.
(b) *Volatility:* The expected volatility was estimated using peer data of companies in the biopharmaceutical industry with similar equity plans.
(c) *Expected life:* The expected life of the award was estimated using peer data of companies in the biopharmaceutical industry with similar equity plans.

Unrecognized stock-based compensation expense related to nonvested options, adjusted for expected forfeitures, was $6.0 million and $0.4 million at December 31, 2011 an 2010, respectively. The unrecognized stock-based compensation expense is expected to be recognized over the weighted-average remaining vesting period of 3.1 years at December 31, 2011.

Common Stock Reserved for Issuance

As of December 31, 2011, the Company reserved shares of common stock for future issuance as follows:

	Options Outstanding	Available for Grant or Future Issuance	Total Shares of Common Stock Reserved
2009 Equity Incentive Plan	903,816	—	903,816
2011 Stock Incentive Plan	31,000	1,357,258	1,388,258
2011 Employee Stock Purchase Plan	—	189,656	189,656
	934,816	1,546,914	2,481,730

8. Share-Based Compensation (Continued)

Employee Stock Purchase Plan

On August 24, 2011, our Board of Directors approved the Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan, or Purchase Plan. Under the Purchase Plan, we are authorized to issue 189,656 shares of common stock to qualified employees. Each year, on the date of our annual meeting of stockholders and at the discretion of our board of directors, the amount of shares reserved for issuance under the 2011 Employee Stock Purchas Plan may be increased by up to the lesser of (x) a number of additional shares our common stock representing 1% of our then-outstanding shares of common stock and (y) 344,828 shares of our common stock. The Purchase Plan will provide for consecutive 6-month offering periods, during which participating employees may elect to have up to 10% of their compensation withheld and applied to the purchase of common stock at the end of each offering period. The purchase price of the common stock will be 85% of the lower of the fair market value of a share of common stock on the first trading date of each offering or the fair market value of a share of common stock on the last trading day of the offering period. The Purchase Plan will terminate on August 24, 2021, the tenth anniversary of the date of initial adoption of the Purchase Plan. The first offering period of the Purchase Plan has not yet been initiated.

9. Commitments

The Company leases office space in Boulder, Colorado, San Francisco, California and Cambridge, U.K. under non-cancelable operating lease agreements. The lease agreements contain periodic rent increases that result in the Company recording deferred rent over the term of certain leases. Rental expense under these leases was approximately $788,000 and $609,000 for the years ended December 31, 2011 and 2010, respectively, and $39,000 from April 20, 2009 (inception) to December 31, 2009. Future minimum rental commitments, by fiscal year and in the aggregate, for the Company's operating leases are provided below (in thousands):

	December 31, 2011
2012	$ 751
2013	389
2014	203
2015	190
2016	
Total future minimum lease payments	$ 1,533

10. License Agreements

CO-101

In November 2009, the Company entered into a license agreement with Clavis Pharma ASA ("Clavis") to develop and commercialize CO-101 in North America, Central America, South America and Europe. Under terms of the license agreement, the Company made an up-front payment to Clavis in the amount $15.0 million, which was comprised of $13.1 million for development costs incurred prior to the execution of the agreement that was recognized as acquired in-process research and development and $1.9 million for the prepayment of preclinical activities to be performed by Clavis. In November 2010, the license agreement was amended to expand the license territory to include Asia and other international markets. The Company made a payment of $10.0 million to Clavis for the territory expansion and recognized the payment as acquired in-process research and development. As part of the amended license agreement, Clavis has also agreed to reimburse up to $3.0 million of the Company's research and development costs for certain CO-101 development activities subject to the Company incurring such costs. For the years ended December 31, 2011 and 2010, the Company incurred expenses for reimbursement of approximately $2.7 million and $0.3 million, respectively, which were recorded as a reduction to research and development expenses. The Company is responsible for all remaining development and commercialization costs of the compound and, if approved, Clavis will be eligible to receive royalties based on the volume of annual net sales achieved. The Company may be required to pay Clavis up to an aggregate of $115.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, the Company may be required to pay Clavis up to an aggregate of $445.0 million in sales milestone payments if certain annual sales targets are met for the CO-101 compound.

Subject to certain conditions set forth in the license agreement, Clavis may elect to co-develop and co-promote CO-101 in Europe. If Clavis were to make this election, it would be required to reimburse the Company for a portion of both past and future development costs. In addition, the milestone payments described above would be reduced, and Clavis would not be entitled to royalties on the net sales in Europe, but would instead share equally in the pretax profits or losses resulting from commercialization activities in Europe.

10. License Agreements (Continued)

CO-1686

In May 2010, the Company entered into a worldwide license agreement with Avila Therapeutics, Inc. ("Avila") to discover, develop and commercialize preclinical covalent inhibitors of mutant forms of the epidermal growth factor receptor gene. CO-1686 was identified as the lead inhibitor candidate developed by Avila under the license agreement. The Company is responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize CO-1686. The Company made an up-front payment of $2.0 million to Avila upon execution of the license agreement which was recognized as acquired in-process research and development expense. The Company is obligated to pay Avila royalties on net sales of CO-1686, based on the volume of annual net sales achieved. Avila has the option to increase royalty rates by electing to reimburse a portion of the development expenses incurred by the Company. This option must be exercised within a limited period of time of Avila's being notified of our intent to pursue regulatory approval of CO-1686 in the United States or European Union as a first line therapy. The Company may be required to pay to Avila up to an aggregate of $119.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, the Company may be required to pay Avila up to an aggregate of $120.0 million in sales milestones if certain annual sales targets are achieved.

Rucaparib

In June 2011, the Company entered into a license agreement with Pfizer Inc. to acquire exclusive global development and commercialization rights to Pfizer's drug candidate PF-01367338, also known as rucaparib. This drug candidate is a small molecule inhibitor of poly (ADP-ribose) polymerase, or PARP, which the Company is developing for the treatment of selected solid tumors. Pursuant to the terms of the license agreement, the Company made an up-front payment by issuing to Pfizer a $7.0 million convertible promissory note with a 5% annual interest rate, due in 2012. The Company is responsible for all development and commercialization costs of rucaparib and, if approved, Pfizer will receive royalties on the net sales of the product. In addition, Pfizer is eligible to receive up to $259 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved.

Upon completion of the Company's initial public offering in November 2011, the principal balance and all accrued and unpaid interest due on this note of $7.2 million was converted into 551,222 shares of common stock.

11. Net Loss Per Common Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock and stock options are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The shares outstanding at the end of the respective periods presented in the table below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect (in thousands):

	Year Ended December 31,		Period from April 20, 2009 (Inception) to December 31, 2009	Cumulative from April 20, 2009 (Inception) to December 31, 2011
	2011	2010		
Common shares under option	935	422	197	935
Convertible preferred stock	—	7,245	7,245	—
Total potential dilutive shares	935	7,667	7,442	935

12. Income Taxes

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31,		Period from April 20, 2009 (Inception) to December 31, 2009
	2011	2010	
Federal income tax (benefit) at statutory rate	(34.0)%	(34.0)%	(34.0)%
State income tax benefit, net of federal benefit	(3.6)	(3.6)	(4.4)
Tax credits	(13.4)	(12.9)	—
Other	(2.7)	0.3	—
Change in valuation allowance	53.7	50.2	38.4
Effective income tax rate	— %	— %	— %

12. Income Taxes (Continued)

The components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31, 2011	December 31, 2010
Deferred tax assets:		
Net operating loss carryforward	$ 26,129	$ 9,386
Tax credit carryforwards	18,167	7,186
Product acquisition costs	11,169	9,229
Share-based compensation expense	322	10
Accrued liabilities and other	79	47
Total deferred tax assets	55,866	25,858
Valuation allowance	(55,342)	(25,510)
Deferred tax assets, net of valuation allowance	524	348
Deferred tax liabilities:		
Prepaid expenses	(435)	(321)
Depreciation	(89)	(27)
Total deferred tax liabilities	(524)	(348)
Net deferred tax assets	$ —	$ —

The realization of deferred tax assets is dependent upon future earnings, and the timing and amount of these future earnings is uncertain. A valuation allowance was established for the net deferred tax asset balance due to management's belief that the realization of these assets is not likely to occur in the foreseeable future. At December 31, 2011, the Company had approximately $63.6 million and $101.4 million of U.S. federal and state net operating loss carryforwards, respectively, which will expire from 2029 to 2031 if not utilized. In addition, the Company had research and development and orphan drug tax credit carryforwards of $18.2 million that will expire from 2029 through 2031 if not utilized. The utilization of the net operating loss carryforwards may be subject to certain IRS limitations associated with changes in the ownership interests of significant stockholders, which may limit the Company's ability to use its net operating loss carryforwards in the future and such limitations could be significant. The Company's federal and state income taxes for the period from inception to December 31, 2011 remain open to an audit.

Tax positions must initially be recognized in the financial statements when it is more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions must initially and subsequently be measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and relevant facts. The Company has not identified any significant uncertain tax positions that require recognition in our financial statements. Our evaluation was performed from inception through December 31, 2011.

The Company recorded an increase to the valuation allowance of $29.8 million and $19.0 million during the year ended December 31, 2011 and 2010, respectively, due primarily to an increase in net operating loss carryforwards and tax credit carryforwards.

The Company may be assessed interest and penalties related to the settlement of tax positions. We will recognize interest and penalties within income tax expense, when assessed. To date, no interest and penalties have been recognized by the Company.

During 2010, the Company was awarded $489,000 under the Qualifying Therapeutic Discovery Project Program (section 48D of the internal revenue code), which the Company elected to receive in the form of a grant. This award has been reflected as other income in the consolidated statement of operations for the year ended December 31, 2010.

13. Employee Benefit Plan

In 2010, the Company established a retirement plan, which is qualified under section 401(k) of the Internal Revenue Code for its U.S. employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the IRS annual limits. The Company matches contributions up to 4% of the eligible employee's compensation or the maximum amount permitted by law. Total expense for contributions made to U.S. employees was $181,000 and $104,000 for the years ended December 31, 2011 and 2010, respectively. The Company's international employees participate in retirement plans governed by the local laws in effect for the country in which they reside. The Company made matching contributions to international employees of $64,000 and $41,000 for the year ended December 31, 2011 and 2010, respectively.

14. Subsequent Events

In January 2012, the U.S. Food and Drug Administration (FDA) accepted our investigational new drug (IND) application to begin clinical investigation of CO-1686. With the FDA's acceptance of the IND application, we made payment of $4.0 million to Avila Therapeutics, Inc. as required by the license agreement we entered into with Avila for CO-1686 and recognized the payment as acquired in-process research and development.

15. Quarterly Information (Unaudited)

The results of operations on a quarterly basis for the years ended December 31, 2011 and 2010 were as follows:

	(In thousands, except per share data)							
	March 31, 2011	June 30, 2011	Sept. 30, 2011	Dec. 31, 2011(2)	March 31, 2010	June 30, 2010	Sept. 30, 2010	Dec. 31, 2010(1)
Revenues	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Expenses:								
Research and development	7,041	9,679	11,566	12,440	3,259	4,683	5,730	8,651
General and administrative	1,405	1,705	1,714	2,036	830	1,152	1,083	1,237
Acquired in-process research and development	—	7,000	—	—	—	2,000	—	10,000
Operating loss	(8,446)	(18,384)	(13,280)	(14,476)	(4,089)	(7,835)	(6,813)	(19,888)
Other income (expense), net	118	(115)	(555)	(405)	(2)	(70)	412	455
Loss before income taxes	(8,328)	(18,499)	(13,835)	(14,881)	(4,091)	(7,905)	(6,401)	(19,433)
Income Taxes	—	—	—	(27)	—	—	—	—
Net loss	$(8,328)	$(18,499)	$(13,835)	$(14,908)	$(4,091)	$(7,905)	$(6,401)	$ (19,433)
Net loss per share: basic and diluted	$ (6.64)	$ (14.32)	$ (10.73)	$ (1.30)	$ (3.09)	$ (5.98)	$ (4.83)	$ (14.60)
Weighted average shares: basic and diluted	1,254	1,292	1,289	11,498	1,322	1,322	1,326	1,331

(1) In November 2010, the Company was awarded approximately $489,000 under the Qualifying Therapeutic Discovery Project program and the amount was recorded to Other income (expense), net.

(2) In November 2011, the Company completed its initial public offering (“IPO”), which resulted in net proceeds of $129.4 million from the issuance of 10,700,000 shares of common stock, which includes the sale of 700,000 of shares under the underwriters’ over-allotment option . In connection with the initial public offering, all of the outstanding shares of the Company’s convertible preferred stock and convertible promissory notes payable and related accrued interest were converted into 10,002,311shares of common stock.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc.
3.2	Amended and Restated Bylaws of Clovis Oncology, Inc.
4.1(3)	Form of Common Stock Certificate of Clovis Oncology, Inc.
4.2(1)	Clovis Oncology Inc. Investor Rights Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc., certain investors named therein.
10.1*(1)	Amended and Restated License Agreement, dated as of November 10, 2010, by and between Clovis Oncology, Inc. and Clavis Pharma ASA.
10.2*(4)	Amended and Restated Strategic License Agreement, dated as of June 16, 2011, by and between Clovis Oncology, Inc. and Avila Therapeutics, Inc.
10.3*(4)	License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc.
10.4+(1)	Clovis Oncology, Inc. 2009 Equity Incentive Plan.
10.5+(4)	Clovis Oncology, Inc. 2011 Equity Incentive Plan.
10.6+(1)	Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement.
10.7+(4)	Form of Clovis Oncology, Inc. 2011 Equity Incentive Plan Stock Option Agreement.
10.8+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.9+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Erle T. Mast.
10.10+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.11+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Andrew R. Allen.
10.12+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and John C. Reed.
10.13+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein.
10.14+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and James C. Blair.
10.15+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Edward J. McKinley.
10.16+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen.
10.17+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and M. James Barrett.
10.18+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Brian G. Atwood.
10.19+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.20+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
10.21+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.22+(1)	Indemnification Agreement, dated as of May 13, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.23+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.24+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
10.25+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.26+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.27*(4)	Companion Diagnostics Agreement, dated as of April 19, 2011, by and between Clovis Oncology, Inc. and Roche Molecular Systems, Inc.
10.28*(4)	Master Service Agreement, dated as of March 23, 2010, by and between Clovis Oncology, Inc. and Ventana Medical Systems, Inc., together with the related Individual Project Agreement, dated as of March 25, 2010.
10.29+(4)	Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan.
10.30+(4)	Clovis Oncology, Inc. 2011 Cash Bonus Plan.
10.31+(4)	Offer of Employment Letter, dated August 5, 2011, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
21.1(1)	List of Subsidiaries of Clovis Oncology, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.

Exhibit Number	Exhibit Description
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on June 23, 2011.
(2) Filed as an exhibit with Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on August 5, 2011.
(3) Filed as an exhibit with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on August 31, 2011.
(4) Filed as an exhibit with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on October 31, 2011.
+ Indicates management contract or compensatory plan.
* Confidential treatment has been granted with respect to portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

Exhibit 3.1

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION OF
CLOVIS ONCOLOGY, INC.

The undersigned, being a duly appointed and authorized officer of Clovis Oncology, Inc., a corporation organized and existing under the laws of the State of Delaware (the "**Corporation**"), does hereby certify, on behalf of the Corporation and not in his individual capacity, as follows:

1. The name of the Corporation is Clovis Oncology, Inc.

2. The Corporation's original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on April 20, 2009, which was amended and restated on May 15, 2009, and which was further amended on May 25, 2011 and September 22, 2011.

3. Pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware (the " **DGCL**"), this Amended and Restated Certificate of Incorporation of the Corporation restates and integrates and further amends the provisions of the Corporation's Amended and Restated Certificate of Incorporation, as amended.

4. This Amended and Restated Certificate of Incorporation of the Corporation was duly authorized in accordance with Sections 141, 228, 242 and 245 of the DGCL, and is executed, acknowledged and filed in accordance with Section 103 of the DGCL.

5. The text of the Amended and Restated Certificate of Incorporation of the Corporation is hereby restated and further amended to read in its entirety as follows:

ARTICLE I

The name of the corporation is Clovis Oncology, Inc. (the "**Corporation**").

ARTICLE II

The address of the Corporation's registered office in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle, 19801. The name of the registered agent at such address is The Corporation Trust Company.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "**DGCL**").

ARTICLE IV

The total number of shares of stock that the Corporation shall have authority to issue is 110,000,000 shares, consisting of 100,000,000 shares of Common Stock, $0.001 par value per share (the "**Common Stock**"), and 10,000,000 shares of Preferred Stock, $0.001 par value per share (the " **Preferred Stock**").

The rights, powers, preferences, privileges and restrictions granted to or imposed upon the Common Stock and Preferred Stock are as set forth in Article V below.

ARTICLE V

The terms and provisions of the Common Stock and Preferred Stock are as follows:

1. Common Stock.

(a) General. The voting, dividend and liquidation rights of the holders of Common Stock are subject to and qualified by the rights of the holders of Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of Preferred Stock of any series.

(b) Voting. Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders for their vote; *provided*, *however*, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series of Preferred Stock are entitled, either separately or together as a class with the holders of one or more other series of Preferred Stock, to vote thereon by law or pursuant to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock). There shall be no cumulative voting.

(c) Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as, if and when determined by the Board of Directors of the Corporation (the "**Board of Directors**") and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

(d) Liquidation. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Corporation, subject to the rights of any then outstanding Preferred Stock, if any, the holders of the Common Stock shall share on a pro rata basis in all distributions of assets available for distribution to stockholders pursuant to such liquidation.

(e) Change in Authorized Common Stock. Except as otherwise provided in this Amended and Restated Certificate of Incorporation, the number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares of Common Stock then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote (voting together as a single class on an as-converted basis) irrespective of the provisions of Section 242(b)(2) of the DGCL and the holders of Common Stock shall not be entitled to any separate class vote in connection with any such increase or decrease of the aggregate number of authorized shares of Common Stock.

2. Preferred Stock.

(a) Preferred Stock may be issued from time to time in one or more series pursuant to a resolution or resolutions for such issue duly adopted by the Board of Directors (authority to do so being hereby expressly vested in the Board of Directors). The Board of Directors is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, of any wholly unissued series of Preferred Stock, including without limitation authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption, redemption price or prices, and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing.

(b) The Board of Directors is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, the number of which was fixed by it, subsequent to the issuance of shares of such series then outstanding, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in this Amended and Restated Certificate of Incorporation or the resolution of the Board of Directors originally fixing the number of shares of such series. If the number of shares of any series is so decreased, then the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

ARTICLE VI

Unless otherwise set forth herein, and subject to the rights of the holders of Preferred Stock, the number of directors which constitute the Board of Directors shall be no less than three, as fixed from time to time exclusively by the Board of Directors pursuant to a resolution adopted by a majority of the members of the Board of Directors. At each annual meeting of stockholders, directors of the Corporation shall be elected to hold office until the expiration of the term for which they are elected and until their successors have been duly elected and qualified or until their earlier resignation or removal.

Effective upon the date of filing of this Amended and Restated Certificate of Incorporation (the " **Effective Date**"), the directors of the Corporation shall be divided into three classes as nearly equal in size as is practicable, hereby designated Class I, Class II and Class III. The Board of Directors may assign members of the Board of Directors already in office to such classes at the time such classification becomes effective. The term of office of the initial Class I directors shall expire at the first regularly scheduled annual meeting of stockholders following the Effective Date, the term of office of the initial Class II directors shall expire at the second annual meeting of stockholders following the Effective Date and the term of office of the initial Class III directors shall expire at the third annual meeting of stockholders following the Effective Date. At each annual meeting of stockholders, commencing with the first regularly scheduled annual meeting of stockholders following the Effective Date, each of the successors elected to replace the directors of a class whose term shall have expired at such annual meeting shall be elected to hold office until the third annual meeting next succeeding his or her election and until his or her respective successor shall have been duly elected and qualified.

If the number of directors is hereafter changed, any newly created directorships or decrease in directorships shall be so apportioned among the classes as to make all classes as nearly equal in number as is practicable, provided that no decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Any director may be removed from office by the stockholders only for cause. Vacancies occurring on the Board of Directors for any reason and newly created directorships resulting from an increase in the authorized number of directors may be filled only by vote of a majority of the remaining members of the Board of Directors, although less than a quorum, or by a sole remaining director, at any meeting of the Board of Directors. A person so elected by the Board of Directors to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall be duly elected and qualified.

During any period when the holders of any series of Preferred Stock have the right to elect additional directors as provided for or fixed pursuant to the provisions of Article V hereof, then upon commencement and for the duration of the period during which such right continues: (i) the then otherwise total authorized number of directors of the Corporation shall automatically be increased by such specified number of directors, and the holders of such Preferred Stock shall be entitled to elect the additional directors so provided for or fixed pursuant to said provisions, and (ii) each such additional director shall serve until such director's successor shall have been duly elected and qualified, or until such director's right to hold such office terminates pursuant to said provisions, whichever occurs earlier, subject to his earlier death, disqualification, resignation or removal. Except as otherwise provided by the Board of Directors in the resolution or resolutions establishing such series, whenever the holders of any series of Preferred Stock having such right to elect additional directors are divested of such right pursuant to the provisions of such stock, the terms of office of all such additional directors elected by the holders of such stock, or elected to fill any vacancies resulting from the death, resignation, disqualification or removal of such additional directors, shall forthwith terminate and the total authorized number of directors of the Corporation shall be reduced accordingly.

ARTICLE VII

Meetings of the stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. A special meeting of the stockholders may be called, and business to be considered at any such meeting may be proposed, at any time exclusively by the Chairman of the Board of Directors, the Chief Executive Officer or a majority of the members of the Board of Directors. Subject to the rights of the holders of any Preferred Stock, no stockholder shall have the power to require the Board of Directors to call a special meeting of stockholders or to propose business at a special meeting of stockholders. The books of the Corporation may be kept (subject to any provision contained in the statute) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

ARTICLE VIII

Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

ARTICLE IX

No action required to be taken or that may be taken at any meeting of stockholders may be taken without a meeting, and no action shall be taken by the stockholders by written consent; *provided*, *however*, that, to the extent expressly permitted by the certificate of designation relating to one or more series of Preferred Stock, any action required or permitted to be taken by the holders of such series of Preferred Stock, voting separately as a series or separately as a class with one or more other such series, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding shares of the relevant class or series having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Corporation by delivery to its registered office in Delaware, its principal place of business, or to an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded.

ARTICLE X

In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, alter, amend or repeal the Bylaws of the Corporation.

Notwithstanding any other provisions of this Amended and Restated Certificate of Incorporation or any provision of law that might otherwise permit a lesser or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the capital stock of the Corporation, the affirmative vote of the holders of not less than 80 percent of the voting power of the outstanding shares of the Corporation then entitled to vote upon the election of directors, voting together as a single class, shall be required to amend or repeal, or to adopt (i) any provision inconsistent with, Article VI, Article VII, Article VIII, Article IX or this Article X of this Amended and Restated Certificate of Incorporation or (ii) any provision of the Bylaws of the Corporation.

ARTICLE XI

1. Indemnification of Directors and Officers in Third Party Proceedings . Subject to the other provisions of this Article XI, the Corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a " **Proceeding**") (other than an action by or in the right of the Corporation) by reason of the fact that such person is or was a director or officer of the Corporation, or is or was a director or officer of the Corporation serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person

in connection with such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

2. Indemnification of Directors and Officers in Actions by or in the Right of the Corporation . Subject to the other provisions of this Article XI, the Corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed Proceeding by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that such person is or was a director or officer of the Corporation, or is or was a director or officer of the Corporation serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation; except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

3. Successful Defense. To the extent that a present or former director or officer of the Corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding described in section 2 or section 3 of this Article XI, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

4. Indemnification of Others. Subject to the other provisions of this Article XI, the Corporation shall have power to indemnify its employees and agents to the extent not prohibited by the DGCL or other applicable law. The Board shall have the power to delegate the determination of whether employees or agents shall be indemnified.

5. Advanced Payment of Expenses. Expenses (including attorneys' fees) incurred by an officer or director of the Corporation in defending any Proceeding shall be paid by the Corporation in advance of the final disposition of such Proceeding upon receipt of a written request therefor (together with documentation reasonably evidencing such expenses) and an undertaking by or on behalf of such officer or director to repay such amounts if it shall ultimately be determined that such person is not entitled to be indemnified by the Corporation under this Article XI or the DGCL. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents may be so paid upon such terms and conditions, if

any, as the Corporation deems appropriate. The right to advancement of expenses shall not apply to any Proceeding for which indemnity is excluded pursuant to these bylaws, but shall apply to any Proceeding referenced in section 6(ii) or 6(iii) of this Article XI prior to a determination that the person is not entitled to be indemnified by the Corporation.

Notwithstanding the foregoing, unless otherwise determined pursuant to section 7 of this Article XI, no advance shall be made by the Corporation to an officer of the Corporation (except in the event that such officer is or was a director of the Corporation, in which event this paragraph shall not apply) in any Proceeding if a determination is reasonably and promptly made (i) by a majority vote of the directors who are not parties to such Proceeding, even though less than a quorum, or (ii) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, that facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the Corporation.

6. Limitation on Indemnification. Subject to the requirements in section 3 of this Article XI and the DGCL, the Corporation shall not be obligated to indemnify any person pursuant to this Article XI in connection with any Proceeding (or any part of any Proceeding):

(i) for which payment has actually been made to or on behalf of such person under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;

(ii) for an accounting or disgorgement of profits pursuant to Section 16(b) of the 1934 Act, or similar provisions of federal, state or local statutory law or common law, if such person is held liable therefor (including pursuant to any settlement arrangements);

(iii) for any reimbursement of the Corporation by such person of any bonus or other incentive-based or equity-based compensation or of any profits realized by such person from the sale of securities of the Corporation, as required in each case under the 1934 Act (including any such reimbursements that arise from an accounting restatement of the Corporation pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the " **Sarbanes-Oxley Act**"), or the payment to the Corporation of profits arising from the purchase and sale by such person of securities in violation of Section 306 of the Sarbanes-Oxley Act), if such person is held liable therefor (including pursuant to any settlement arrangements);

(iv) initiated by such person, including any Proceeding (or any part of any Proceeding) initiated by such person against the Corporation or its directors, officers, employees, agents or other indemnitees, unless (a) the Board authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (b) the Corporation provides the indemnification, in its sole discretion, pursuant to the powers vested in the Corporation under applicable law, (c) otherwise required to be made under section 7 of this Article XI or (d) otherwise required by applicable law; or

(v) if prohibited by applicable law.

7. Determination; Claim. If a claim for indemnification or advancement of expenses under this Article XI is not paid by the Corporation or on its behalf within 90 days after receipt by the Corporation of a written request therefor, the claimant shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of expenses. To the extent not prohibited by law, the Corporation shall indemnify such person against all expenses actually and reasonably incurred by such person in connection with any action for indemnification or advancement of expenses from the Corporation under this Article XI, to the extent such person is successful in such action, and, if requested by such person, shall advance such expenses to such person, subject to the provisions of section 5 of this Article XI. In any such suit, the Corporation shall, to the fullest extent not prohibited by law, have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.

8. Non-Exclusivity of Rights. The indemnification and advancement of expenses provided by, or granted pursuant to, this Article XI shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation or any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. The Corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advancement of expenses, to the fullest extent not prohibited by the DGCL or other applicable law.

9. Insurance. The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such liability under the provisions of the DGCL.

10. Survival. The rights to indemnification and advancement of expenses conferred by this Article XI shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

11. Effect of Repeal or Modification. Any amendment, alteration or repeal of this Article XI shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to such amendment, alteration or repeal.

12. Certain Definitions. For purposes of this Article XI, references to the "**Corporation**" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent

corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article XI with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued. For purposes of this Article XI, references to " **other enterprises**" shall include employee benefit plans; references to "**fines**" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to " **serving at the request of the Corporation**" shall include any service as a director, officer, employee or agent of the Corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "**not opposed to the best interests of the Corporation**" as referred to in this Article XI.

ARTICLE XII

Subject to Article X above, the Corporation reserves the right to amend, alter, change or repeal any provision contained in this Amended and Restated Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon the stockholders herein are granted subject to this reservation.

ARTICLE XIII

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or agent of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or the Corporation's certificate of incorporation or bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine, in each such case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article XIII.

IN WITNESS WHEREOF, Clovis Oncology, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by Patrick J. Mahaffy, a duly authorized officer of the Corporation, on November 21, 2011.

/s/ Patrick J. Mahaffy

Patrick J. Mahaffy,
President and Chief Executive Officer

Exhibit 3.2

AMENDED AND RESTATED

BYLAWS OF

CLOVIS ONCOLOGY, INC.

Effective November 21, 2011

TABLE OF CONTENTS

BYLAWS

ARTICLE I—MEETINGS OF STOCKHOLDERS

1.1 ***Place of Meetings***. Meetings of stockholders of Clovis Oncology, Inc. (the "**Company**") shall be held at any place, within or outside the State of Delaware, determined by the Company's board of directors (the "**Board**"). The Board may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the General Corporation Law of the State of Delaware (the "**DGCL**"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Company's principal executive office.

1.2 ***Annual Meeting***. An annual meeting of stockholders shall be held at such date, at such time and at such place, as may be designated by the Board from time to time and stated in the Company's notice of the meeting. Directors shall be elected and any other proper business may be transacted at the annual meeting. The Board of Directors may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled by the Board of Directors.

1.3 ***Special Meeting***. A special meeting of the stockholders may be called, and business to be considered at any such meeting may be proposed, at any time exclusively by the Chairperson of the Board, the Chief Executive Officer or a majority of the members of the Board. The Board of Directors may postpone, reschedule or cancel any special meeting of stockholders previously scheduled by the Board of Directors, the Chairperson of the Board or the Chief Executive Officer. Business transacted at any special meeting of stockholders shall be limited to the purposes stated in the notice.

If any person(s) other than the Board calls a special meeting, the request shall:

(i) be in writing;

(ii) specify the time of such meeting and the general nature of the business proposed to be transacted; and

(iii) be delivered personally or sent by registered mail or by facsimile transmission to the Chairperson of the Board, the Chief Executive Officer, the President (in the absence of a Chief Executive Officer) or the Secretary of the Company.

The officer(s) receiving the request shall cause notice to be promptly given to the stockholders entitled to vote at such meeting, in accordance with these bylaws, that a meeting will be held at the time requested by the person or persons calling the meeting. No business may be transacted at such special meeting other than the business specified in such notice to stockholders. Nothing contained in this paragraph of this **section 1.3** shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board may be held.

1.4 ***Notice of Stockholders' Meetings***. Whenever stockholders are required or permitted to take any action at a meeting, a notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for determining the stockholders entitled to notice of the meeting), and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Except as otherwise provided in

the DGCL, the certificate of incorporation or these bylaws, the notice of any meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

1.5 ***Advance Notice***

(i) *Advance Notice of Stockholder Business at Annual Meeting* . At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be brought: (A) pursuant to the Company's proxy materials with respect to such meeting, (B) by or at the direction of the Board or a committee thereof, or (C) by a stockholder of the Company who (1) is a stockholder of record at the time of the giving of the notice required by this **section 1.5** and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has timely complied in proper written form with the notice procedures set forth in this **section 1.5**. In addition, for business to be properly brought before an annual meeting by a stockholder, such business must be a proper matter for stockholder action pursuant to these bylaws and applicable law. Except for proposals properly made in accordance with Rule 14a-8 under the Securities and Exchange Act of 1934, and the rules and regulations thereunder (as so amended and inclusive of such rules and regulations) (the " **1934 Act**"), and included in the notice of meeting given by or at the direction of the Board, for the avoidance of doubt, clause (C) above shall be the exclusive means for a stockholder to bring business before an annual meeting of stockholders.

(a) To comply with clause (C) of **section 1.5** above, a stockholder's notice must set forth all information required under this **section 1.5** and must be timely received by the secretary of the Company. To be timely, a stockholder's notice must be received by the secretary at the principal executive offices of the Company not later than the 90th day nor earlier than the 120th day before the one-year anniversary of the preceding year's annual meeting; *provided*, *however*, that in the event that no annual meeting was held in the previous year or if the date of the annual meeting is advanced by more than 30 days prior to or delayed by more than 60 days after the one-year anniversary of the date of the previous year's annual meeting, then, for notice by the stockholder to be timely, it must be so received by the secretary not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of (i) the 90th day prior to such annual meeting, or (ii) the tenth day following the day on which Public Announcement (as defined below) of the date of such annual meeting is first made. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described in this **section 1.5(i)**. "**Public Announcement**" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the Company with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act.

(b) To be in proper written form, a stockholder's notice to the secretary must set forth as to each matter of business the stockholder intends to bring before the annual meeting: (1) a brief description of the business intended to be brought before the annual meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend these bylaws, the language of the proposed amendment) and the reasons for conducting such business at the annual meeting, (2) the name and address, as they appear on the Company's books, of the stockholder proposing such business and any Stockholder Associated Person (as defined below), (3) the class and number of shares of the Company that are held of record or are beneficially owned by the stockholder or any Stockholder Associated Person and any derivative positions held or beneficially held by the stockholder or any Stockholder Associated Person, (4) whether and the

extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of such stockholder or any Stockholder Associated Person with respect to any securities of the Company, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit from share price changes for, or to increase or decrease the voting power of, such stockholder or any Stockholder Associated Person with respect to any securities of the Company, (5) any material interest of the stockholder or a Stockholder Associated Person in such business, and (6) a statement whether either such stockholder or any Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of at least the percentage of the Company's voting shares required under applicable law to carry the proposal (such information provided and statements made as required by clauses (1) through (6), a " **Business Solicitation Statement**"). In addition, to be in proper written form, a stockholder's notice to the secretary must be supplemented not later than ten days following the record date for notice of the meeting to disclose the information contained in clauses (3) and (4) above as of the record date for notice of the meeting. For purposes of this **section 1.5**, a "**Stockholder Associated Person**" of any stockholder shall mean (i) any person controlling, directly or indirectly, or acting in concert with, such stockholder, (ii) any beneficial owner of shares of stock of the Company owned of record or beneficially by such stockholder and on whose behalf the proposal or nomination, as the case may be, is being made, or (iii) any person controlling, controlled by or under common control with such person referred to in the preceding clauses (i) and (ii).

(c) Without exception, no business shall be conducted at any annual meeting except in accordance with the provisions set forth in this **section 1.5** and, if applicable, **section 1.5(ii)**. In addition, business proposed to be brought by a stockholder may not be brought before the annual meeting if such stockholder or a Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Business Solicitation Statement applicable to such business or if the Business Solicitation Statement applicable to such business contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that business was not properly brought before the annual meeting and in accordance with the provisions of this **section 1.5**, and, if the chairperson should so determine, he or she shall so declare at the annual meeting that any such business not properly brought before the annual meeting shall not be conducted. Notwithstanding the foregoing provisions of this **section 1.5(i)**, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual meeting of stockholders of the Company to propose business, such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Company. For purposes of this **section 1.5(i)**, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting of stockholders.

(ii) *Advance Notice of Director Nominations at Annual Meeting*. Notwithstanding anything in these bylaws to the contrary, only persons who are nominated in accordance with the procedures set forth in this **section 1.5(ii)** shall be eligible for election or re-election as directors at an annual meeting of stockholders. Nominations of persons for election or re-election to the Board of the Company shall be made at an annual meeting of stockholders only (A) by or at the direction of the Board or a committee thereof or (B) by a stockholder of the Company who (1) was a stockholder of record at the time of the giving of the notice required by this **section 1.5(ii)** and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has complied with the notice procedures set forth in this **section 1.5(ii)**. In addition to any other applicable requirements, for a nomination to be made by a stockholder, the stockholder must have given timely notice thereof in proper written form to the secretary of the Company.

(a) To comply with clause (B) of **section 1.5(ii)** above, a nomination to be made by a stockholder must set forth all information required under this **section 1.5(ii)** and must be received by the secretary of the Company at the principal executive offices of the Company at the time set forth in, and in accordance with, the final three sentences of **section 1.5(i)(a)** above.

(b) To be in proper written form, such stockholder's notice to the secretary must set forth:

(1) as to each person (a "**nominee**") whom the stockholder proposes to nominate for election or re-election as a director: (A) the name, age, business address and residence address of the nominee, (B) the principal occupation or employment of the nominee, (C) the class and number of shares of the Company that are held of record or are beneficially owned by the nominee and any derivative positions held or beneficially held by the nominee, (D) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of the nominee with respect to any securities of the Company, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of the nominee, (E) a description of all arrangements or understandings between the stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nominations are to be made by the stockholder, (F) a written statement executed by the nominee acknowledging that as a director of the Company, the nominee will owe a fiduciary duty under Delaware law with respect to the Company and its stockholders, and (G) any other information relating to the nominee that would be required to be disclosed about such nominee if proxies were being solicited for the election or re-election of the nominee as a director, or that is otherwise required, in each case pursuant to Regulation 14A under the 1934 Act (including without limitation the nominee's written consent to being named in the proxy statement, if any, as a nominee and to serving as a director if elected or re-elected, as the case may be); and

(2) as to such stockholder giving notice, (A) the information required to be provided pursuant to clauses (2) through (5) of **section 1.5(i)(b)** above, and the supplement referenced in the second sentence of **section 1.5(i)(b)** above (except that the references to "business" in such clauses shall instead refer to nominations of directors for purposes of this paragraph), and (B) a statement whether either such stockholder or Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of a number of the Company's voting shares reasonably believed by such stockholder or Stockholder Associated Person to be necessary to elect or re-elect such nominee(s) (such information provided and statements made as required by clauses (A) and (B) above, a "**Nominee Solicitation Statement**").

(c) At the request of the Board, any person nominated by a stockholder for election or re-election as a director must furnish to the secretary of the Company (1) that information required to be set forth in the stockholder's notice of nomination of such person as a director as of a date subsequent to the date on which the notice of such person's nomination was given and (2) such other information as may reasonably be required by the Company to determine the eligibility of such proposed nominee to serve as an independent director or audit committee financial expert of the Company under applicable law, securities exchange rule or regulation, or any publicly-disclosed corporate governance guideline or committee charter of the Company and (3) that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such nominee; in the absence of the furnishing of such information if requested, such stockholder's nomination shall not be considered in proper form pursuant to this **section 1.5(ii)**.

(d) Without exception, no person shall be eligible for election or re-election as a director of the Company at an annual meeting of stockholders unless nominated in accordance with the provisions set forth in this **section 1.5(ii)**. In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or if the Nominee Solicitation Statement applicable to such nominee contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that a nomination was not made in accordance with the provisions prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the annual meeting, and the defective nomination shall be disregarded. Notwithstanding the foregoing provisions of this **section 1.5(ii)**, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual meeting of stockholders of the Company to present a nomination, such nomination shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Company. For purposes of this **section 1.5(ii)**, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting of stockholders.

(e) Notwithstanding anything in this **section 1.5(ii)** to the contrary, in the event that the number of directors to be elected to the Board at the annual meeting is increased effective after the time period for which nominations would otherwise be due under this **section 1.5(ii)** and there is no public announcement by the Company naming the nominees for the additional directorships at least one hundred (100) days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice required by this **section 1.5(ii)** shall also be considered timely, but only with respect to nominees for the additional directorships, if it shall be delivered to the Secretary at the principal executive offices of the Company not later than the close of business on the tenth (10th) day following the day on which such Public Announcement is first made by the Company.

(iii) *Advance Notice of Director Nominations at Special Meetings* .

(a) For a special meeting of stockholders at which directors are to be elected or re-elected, nominations of persons for election or re-election to the Board shall be made only (1) by or at the direction of the Board or a committee thereof or (2) by any stockholder of the Company who (A) is a stockholder of record at the time of the giving of the notice required by this **section 1.5(iii)** and on the record date for the determination of stockholders entitled to vote at the special meeting and (B) delivers a timely written notice of the nomination to the secretary of the Company that includes the information set forth in **sections 1.5(ii)(b)** and **1.5(ii)(c)** above. To be timely, such notice must be received by the secretary at the principal executive offices of the Company not later than the close of business on the later of the 90th day prior to such special meeting or the tenth day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the Board to be elected or re-elected at such meeting. A person shall not be eligible for election or re-election as a director at a special meeting unless the person is nominated (i) by or at the direction of the Board or (ii) by a stockholder in accordance with the notice procedures set forth in this **section 1.5(iii)**. In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or if the Nominee Solicitation Statement applicable to such nominee contains

an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. Notwithstanding the foregoing provisions of this **section 1.5(iii)**, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at a special meeting of stockholders of the Company to present a nomination, such nomination shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Company. For purposes of this **section 1.5(iii)**, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at such special meeting and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at such special meeting.

(b) The chairperson of the special meeting shall, if the facts warrant, determine and declare at the meeting that a nomination or business was not made in accordance with the procedures prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the meeting, and the defective nomination or business shall be disregarded.

(iv) *Other Requirements and Rights*. In addition to the foregoing provisions of this **section 1.5**, a stockholder must also comply with all applicable requirements of state law and of the 1934 Act and the rules and regulations thereunder with respect to the matters set forth in this **section 1.5**. Nothing in this **section 1.5** shall be deemed to affect any rights of:

(a) a stockholder to request inclusion of proposals in the Company's proxy statement pursuant to Rule 14a 8 (or any successor provision) under the 1934 Act;

(b) the Company to omit a proposal from the Company's proxy statement pursuant to Rule 14a 8 (or any successor provision) under the 1934 Act; or

(c) holders of any series of Preferred Stock to elect directors pursuant to any applicable provision of the certificate of incorporation.

1.6 ***Quorum***. Except as otherwise provided by law, the certificate of incorporation or these bylaws, at each meeting of stockholders the presence in person or by proxy of the holders of shares of stock having a majority of the votes which could be cast by the holders of all outstanding shares of stock entitled to vote at the meeting shall be necessary and sufficient to constitute a quorum. Where a separate vote by a class or series or classes or series is required, a majority of the outstanding shares of such class or series or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter, except as otherwise provided by law, the certificate of incorporation or these bylaws.

If, however, such quorum is not present or represented at any meeting of the stockholders, then either (i) the chairperson of the meeting, or (ii) the stockholders entitled to vote at the meeting, present in person or represented by proxy, shall have the power to adjourn the meeting from time to time, in the manner provided in **section 1.7**, until a quorum is present or represented.

1.7 ***Adjourned Meeting; Notice***. Any meeting of stockholders, annual or special, may adjourn from time to time to reconvene at the same or some other place, and notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Company may transact any business which might have been transacted at the original

meeting. If the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for determination of stockholders entitled to vote is fixed for the adjourned meeting, the Board shall fix as the record date for determining stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote at the adjourned meeting, and shall give notice of the adjourned meeting to each stockholder of record as of the record date so fixed for notice of such adjourned meeting.

1.8 ***Conduct of Business***. Meetings of stockholders shall be presided over by the Chairperson of the Board, if any, or in his or her absence by the Vice Chairperson of the Board, if any, or in the absence of the foregoing persons by the Chief Executive Officer, or in the absence of the foregoing persons by the President, or in the absence of the foregoing persons by a Vice President, or in the absence of the foregoing persons by a chairperson designated by the Board, or in the absence of such designation by a chairperson chosen at the meeting. The Secretary shall act as secretary of the meeting, but in his or her absence the chairperson of the meeting may appoint any person to act as secretary of the meeting. The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting by the person presiding over the meeting. The Board may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate.

Except to the extent inconsistent with such rules and regulations as adopted by the Board, the person presiding over any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting, to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such presiding person, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the presiding person of the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the presiding person of the meeting shall determine; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. The presiding person at any meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting, shall, if the facts warrant, determine and declare to the meeting that a matter or business was not properly brought before the meeting and if such presiding person should so determine, such presiding person shall so declare to the meeting and any such matter or business not properly brought before the meeting shall not be transacted or considered. Unless and to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

1.9 ***Voting***. The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of **section 1.12** of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation, each stockholder entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of capital stock held by such stockholder which has voting power upon the matter in question. Voting at meetings of stockholders need not be by written ballot. If authorized by the Board, such requirement of a written ballot shall be satisfied by a ballot submitted by electronic transmission (as defined in **section 6.2** of these bylaws), *provided* that any such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the stockholder or proxy holder.

Except as otherwise required by law, the certificate of incorporation or these bylaws, in all matters other than the election of directors, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of the stockholders. Except as otherwise required by law, the certificate of incorporation or these bylaws, directors shall be elected by a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Where a separate vote by a class or series or classes or series is required, in all matters other than the election of directors, the affirmative vote of the majority of the affirmative voting power of the shares of such class or series or classes or series present in person or represented by proxy at the meeting shall be the act of such class or series or classes or series, except as otherwise provided by law, the certificate of incorporation or these bylaws.

1.10 ***Inspectors of Election***. Before any meeting of stockholders, the Board shall appoint one or more inspectors to act at the meeting or its adjournment and make a written report thereof. If any person appointed as inspector fails to appear or fails or refuses to act, then the Chairperson of the meeting may, and upon the request of any stockholder or a stockholder's proxy shall, appoint a person to fill that vacancy.

Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath to execute faithfully the duties of inspector with strict impartiality and according to the best of his or her ability. The inspector or inspectors so appointed and designated shall (i) ascertain the number of shares of capital stock of the Company outstanding and the voting power of each share, (ii) determine the shares of capital stock of the Company represented at the meeting and the validity of proxies and ballots, (iii) count all votes and ballots, (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors, and (v) certify their determination of the number of shares of capital stock of the Company represented at the meeting and such inspector or inspectors' count of all votes and ballots.

In determining the validity and counting of proxies and ballots cast at any meeting of stockholders of the Company, the inspector or inspectors may consider such information as is permitted by applicable law.

1.11 ***Stockholder Action by Written Consent Without a Meeting***. Any action required by the DGCL to be taken at any annual or special meeting of stockholders of a corporation, or any action which may be taken at any annual or special meeting of such stockholders, must be effected by a duly called meeting and may not be effected by any consent or consents in writing; *provided*, *however*, that, to the extent expressly permitted by the certificate of designation relating to one or more series of Preferred Stock, any action required or permitted to be taken by the holders of such series of Preferred Stock, voting separately as a series or separately as a class with one or more other such series, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding shares of the relevant class or series having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Company by delivery to its registered office in Delaware, its principal place of business, or to an officer or agent of the Company having custody of the book in which proceedings of meetings of stockholders are recorded.

1.12 ***Record Date for Stockholder Notice; Voting***. In order that the Company may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board and which record date:

(i) in the case of determination of stockholders entitled to notice of any meeting of stockholders or adjournment thereof, shall, unless otherwise required by law, not be more than sixty nor less than ten days before the date of such meeting;

(ii) in the case of determination of stockholders for any other action, shall not be more than 60 days prior to such other action; and

(iii) in the case of determination of stockholders entitled to notice of a meeting or an adjournment thereof, if the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination.

If no record date is fixed by the Board:

(i) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held; and

(ii) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, *provided* that the Board may fix a new record date for the adjourned meeting, and in such case shall also fix as the record date for determination of stockholders entitled to vote at such adjourned meeting and stockholders entitled to notice of such adjourned meeting, the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the provisions of Section 213 of the DGCL and this **section 1.12** at the adjourned meeting.

1.13 ***Proxies***. Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy authorized by an instrument in writing or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A written proxy may be in the form of a telegram, cablegram, or other means of electronic transmission which sets forth or is submitted with information from which it can be determined that the telegram, cablegram, or other means of electronic transmission was authorized by the person.

1.14 ***List of Stockholders Entitled to Vote***. The officer who has charge of the stock ledger of the Company shall prepare and make, at least ten days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting (*provided*, *however*, if the record date for

determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Company shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten days prior to the meeting: (i) on a reasonably accessible electronic network, *provided* that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the Company's principal place of business. In the event that the Company determines to make the list available on an electronic network, the Company may take reasonable steps to ensure that such information is available only to stockholders of the Company. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

ARTICLE II—DIRECTORS

2.1 ***Powers***. The business and affairs of the Company shall be managed by or under the direction of the Board, except as may be otherwise provided in the DGCL or the certificate of incorporation.

2.2 ***Number of Directors***. The Board shall consist of one or more members, each of whom shall be a natural person. Unless the certificate of incorporation fixes the number of directors, the number of directors shall be determined from time to time by resolution of the Board. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

2.3 ***Election, Qualification and Term of Office of Directors***. Except as provided in **section 2.4** of these bylaws, directors shall be elected at each annual meeting of stockholders. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors. Each director shall hold office until such director's successor is elected and qualified or until such director's earlier death, resignation or removal.

2.4 ***Resignation and Vacancies***. Any director may resign at any time upon notice given in writing or by electronic transmission to the Company; *provided*, *however*, that if such notice is given by electronic transmission, such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the director. A resignation is effective when the resignation is delivered unless the resignation specifies a later effective date or an effective date determined upon the happening of an event or events. A resignation which is conditioned upon the director failing to receive a specified vote for reelection as a director may provide that it is irrevocable. Unless otherwise provided in the certificate of incorporation or these bylaws, when one or more directors resign from the Board, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective.

Unless otherwise provided in the certificate of incorporation or these bylaws:

(i) Vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.

(ii) Whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the certificate of incorporation, vacancies and newly created directorships of such class or classes or series may only be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected.

A director elected to fill a vacancy or newly created directorship shall be elected for the unexpired term of his or her predecessor in office and shall hold office until the next election of the class for which such elector shall have been chosen and until such director's successor is duly elected and qualified, or until such director's earlier death, resignation or removal.

2.5 ***Place of Meetings; Meetings by Telephone***. The Board may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

2.6 ***Conduct of Business***. Meetings of the Board shall be presided over by the Chairperson of the Board, if any, or in his or her absence by the Vice Chairperson of the Board, if any, or in the absence of the foregoing persons by a chairperson designated by the Board, or in the absence of such designation by a chairperson chosen at the meeting. The Secretary shall act as secretary of the meeting, but in his or her absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.

2.7 ***Regular Meetings***. Regular meetings of the Board may be held without notice at such time and at such place as shall from time to time be determined by the Board.

2.8 ***Special Meetings; Notice***. Special meetings of the Board for any purpose or purposes may be called at any time by the Chairperson of the Board, the Chief Executive Officer, the President, or any two directors.

Notice of the time and place of special meetings shall be:

(i) delivered personally by hand, by courier or by telephone;

(ii) sent by United States first-class mail, postage prepaid;

(iii) sent by facsimile; or

(iv) sent by electronic mail,

directed to each director at that director's address, telephone number, facsimile number or electronic mail address, as the case may be, as shown on the Company's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile or (iii) sent by electronic mail, it shall be delivered or sent at least 24 hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the Company's principal executive office) nor the purpose of the meeting.

2.9 ***Quorum; Voting***. At all meetings of the Board, a majority of the total authorized number of directors shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the Board, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws.

If the certificate of incorporation provides that one or more directors shall have more or less than one vote per director on any matter, every reference in these bylaws to a majority or other proportion of the directors shall refer to a majority or other proportion of the votes of the directors.

2.10 ***Board Action by Written Consent Without a Meeting***. Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

2.11 ***Fees and Compensation of Directors***. Unless otherwise restricted by the certificate of incorporation or these bylaws, the Board shall have the authority to fix the compensation of directors.

2.12 ***Removal of Directors***. Unless otherwise restricted by statute, the certificate of incorporation or these bylaws, any director or the entire Board may be removed by the holders of a majority of the shares then entitled to vote at an election of directors only for cause.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

ARTICLE III — COMMITTEES

3.1 ***Committees of Directors***. The Board may designate one or more committees, each committee to consist of one or more of the directors of the Company. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board or in these bylaws, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Company, and may authorize the seal of the Company to be affixed to all papers that may require it; but no such

committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the Company.

3.2 ***Committee Minutes***. Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

3.3 ***Meetings and Actions of Committees***. Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

(i) **section 2.5** (Place of Meetings; Meetings by Telephone);

(ii) **section 2.7** (Regular Meetings);

(iii) **section 2.8** (Special Meetings; Notice);

(iv) **section 2.9** (Quorum; Voting);

(v) **section 2.10** (Board Action by Written Consent Without a Meeting); and

(vi) **section 6.5** (Waiver of Notice)

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the Board and its members. *However*:

(i) the time of regular meetings of committees may be determined either by resolution of the Board or by resolution of the committee;

(ii) special meetings of committees may also be called by resolution of the Board; and

(iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The Board may adopt rules for the governance of any committee not inconsistent with the provisions of these bylaws.

Any provision in the certificate of incorporation providing that one or more directors shall have more or less than one vote per director on any matter shall apply to voting in any committee or subcommittee, unless otherwise provided in the certificate of incorporation or these bylaws.

3.4 ***Subcommittees***. Unless otherwise provided in the certificate of incorporation, these bylaws or the resolutions of the Board designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

ARTICLE IV—OFFICERS

4.1 ***Officers***. The officers of the Company shall be a President and a Secretary. The Company may also have, at the discretion of the Board, a Chairperson of the Board, a Vice Chairperson of the Board, a Chief Executive Officer, one or more Vice Presidents, a Chief Financial Officer, a Treasurer, one or more Assistant Treasurers, one or more Assistant Secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

4.2 ***Appointment of Officers***. The Board shall appoint the officers of the Company, except such officers as may be appointed in accordance with the provisions of **section 4.3** of these bylaws, subject to the rights, if any, of an officer under any contract of employment.

4.3 ***Subordinate Officers***. The Board may appoint, or empower the Chief Executive Officer or, in the absence of a Chief Executive Officer, the President, to appoint, such other officers and agents as the business of the Company may require. Each of such officers and agents shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the Board may from time to time determine.

4.4 ***Removal and Resignation of Officers***. Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by the Board at any regular or special meeting of the Board or, except in the case of an officer chosen by the Board, by any officer upon whom such power of removal may be conferred by the Board.

Any officer may resign at any time by giving written or electronic notice to the Company; *provided*, *however*, that if such notice is given by electronic transmission, such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the officer. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Company under any contract to which the officer is a party.

4.5 ***Vacancies in Offices***. Any vacancy occurring in any office of the Company shall be filled by the Board or as provided in **section 4.3**.

4.6 ***Representation of Securities of Other Entities***. Unless otherwise directed by the Board, the President or any other person authorized by the Board or the President is authorized to vote, represent and exercise on behalf of the Company all rights incident to any and all securities of any other entity or entities standing in the name of the Company. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

4.7 ***Authority and Duties of Officers***. Except as otherwise provided in these bylaws, the officers of the Company shall have such powers and duties in the management of the Company as may be designated from time to time by the Board and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

ARTICLE V—STOCK

5.1 ***Stock Certificates; Partly Paid Shares***. The shares of the Company shall be represented by certificates, *provided* that the Board may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Company. Every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of the Company by the Chairperson of the Board or Vice-Chairperson of the Board, or the President or a Vice-President, and by the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary of the Company representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer,

transfer agent or registrar before such certificate is issued, it may be issued by the Company with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. The Company shall not have power to issue a certificate in bearer form.

The Company may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, or upon the books and records of the Company in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the Company shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

5.2 ***Special Designation on Certificates***. If the Company is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Company shall issue to represent such class or series of stock; *provided* that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the Company shall issue to represent such class or series of stock, a statement that the Company will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the Company shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to this **section 5.2** or Sections 156, 202(a) or 218(a) of the DGCL or with respect to this **section 5.2** a statement that the Company will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

5.3 ***Lost Certificates***. Except as provided in this **section 5.3**, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Company and cancelled at the same time. The Company may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Company may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Company a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

5.4 ***Dividends***. The Board, subject to any restrictions contained in the certificate of incorporation or applicable law, may declare and pay dividends upon the shares of the Company's capital stock. Dividends may be paid in cash, in property, or in shares of the Company's capital stock, subject to the provisions of the certificate of incorporation.

The Board may set apart out of any of the funds of the Company available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve.

5.5 ***Stock Transfer Agreements***. The Company shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Company to restrict the transfer of shares of stock of the Company of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

5.6 ***Registered Stockholders***. The Company:

(i) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;

(ii) shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares; and

(iii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

5.7 ***Transfers***. Transfers of record of shares of stock of the Company shall be made only upon its books by the holders thereof, in person or by an attorney duly authorized, and, if such stock is certificated, upon the surrender of a certificate or certificates for a like number of shares, properly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer.

ARTICLE VI—MANNER OF GIVING NOTICE AND WAIVER

6.1 ***Notice of Stockholder Meetings***. Notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the Company's records. An affidavit of the Secretary or an Assistant Secretary of the Company or of the transfer agent or other agent of the Company that the notice has been given shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

6.2 ***Notice by Electronic Transmission***. Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the Company under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the Company. Any such consent shall be deemed revoked if:

(i) the Company is unable to deliver by electronic transmission two consecutive notices given by the Company in accordance with such consent; and

(ii) such inability becomes known to the Secretary or an Assistant Secretary of the Company or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

(i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;

(ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;

(iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and

(iv) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the Secretary or an Assistant Secretary or of the transfer agent or other agent of the Company that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

An "**electronic transmission**" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved, and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

Notice by a form of electronic transmission shall not apply to Sections 164, 296, 311, 312 or 324 of the DGCL.

6.3 ***Notice to Stockholders Sharing an Address***. Except as otherwise prohibited under the DGCL, without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Company under the provisions of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the Company. Any stockholder who fails to object in writing to the Company, within 60 days of having been given written notice by the Company of its intention to send the single notice, shall be deemed to have consented to receiving such single written notice.

6.4 ***Notice to Person with Whom Communication is Unlawful***. Whenever notice is required to be given, under the DGCL, the certificate of incorporation or these bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the Company is such as to require the filing of a certificate under the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

6.5 ***Waiver of Notice***. Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

ARTICLE VII — GENERAL MATTERS

7.1 ***Fiscal Year***. The fiscal year of the Company shall be fixed by resolution of the Board and may be changed by the Board.

7.2 ***Seal***. The Company may adopt a corporate seal, which shall be in such form as may be approved from time to time by the Board. The Company may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

7.3 ***Construction; Definitions***. Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both a corporation and a natural person.

ARTICLE VIII — AMENDMENTS

These bylaws may be adopted, amended or repealed by the stockholders entitled to vote. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, alter, amend or repeal these bylaws. The fact that such power has been so conferred upon the directors shall not divest the stockholders of the power, nor limit their power to adopt, amend or repeal bylaws.

A bylaw amendment adopted by stockholders which specifies the votes that shall be necessary for the election of directors shall not be further amended or repealed by the Board.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 333-178283) pertaining to the 2011 Stock Incentive Plan, the 2011 Employee Stock Purchase Plan, and the 2009 Equity Incentive Plan of Clovis Oncology, Inc. of our report dated March 14, 2012, with respect to the consolidated financial statements of Clovis Oncology, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2011.

/s/ Ernst & Young LLP

Denver, CO
March 14, 2012

Exhibit 31.1

I, Patrick J. Mahaffy, certify that:

1. I have reviewed this annual report on Form 10-K of Clovis Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2012

/s/ PATRICK J. MAHAFFY
Patrick J. Mahaffy
Chief Executive Officer

Exhibit 31.2

I, Erle T. Mast, certify that:

1. I have reviewed this annual report on Form 10-K of Clovis Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2012

/s/ ERLE T. MAST
Erle T. Mast
Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

In connection with the Annual Report of Clovis Oncology, Inc., a Delaware corporation (the "Company"), on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission (the "Report"), Patrick H. Mahaffy, as Chief Executive Officer of the Company, does hereby certify, pursuant to § 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350), that to his knowledge:

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

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

Date: March 14, 2012

/s/ PATRICK J. MAHAFFY

Patrick J. Mahaffy
Chief Executive Officer

Exhibit 32.2

CERTIFICATIONS PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

In connection with the Annual Report of Clovis Oncology, Inc., a Delaware corporation (the "Company"), on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission (the "Report"), Erle T. Mast, as Chief Financial Officer of the Company, does hereby certify, pursuant to § 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350), that to his knowledge:

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

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

Date: March 14, 2012

/s/ ERLE T. MAST
Erle T. Mast
Chief Financial Officer